

ORGANOVO HOLDINGS, INC.

Form 10-K

March 15, 2013

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012**

**COMMISSION FILE NUMBER: 000-54621**

**ORGANOVO HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of incorporation)

**27-1488943**  
(IRS Employer Identification No.)

**6275 Nancy Ridge Drive, Suite 110**

**San Diego, CA**  
(Address of principal executive offices)

**92121**  
(Zip code)

**Registrant's telephone number, including area code: 858-550-9994**

Securities registered pursuant to section 12(g) of the Act:

## Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

### Title of each class

#### Common Stock, \$0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting common stock held by non-affiliates based on the closing stock price on June 29, 2012, the last trading day of the registrant's second fiscal quarter, was \$89,329,193. For purposes of this computation only, all executive officers, directors and 10% or greater stockholders have been deemed affiliates.

The number of outstanding shares of the registrant's common stock, as of March 1, 2013 was 62,237,772.

**Table of Contents**

**Organovo Holdings, Inc.**

**Annual Report on Form 10-K**

**For the Fiscal Year Ended December 31, 2012**

**Table of Contents**

	<b>Page</b>
<u>Important Information Regarding Forward-Looking Statements</u>	1
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	12
Item 1B. <u>Unresolved Staff Comments</u>	24
Item 2. <u>Properties</u>	24
Item 3. <u>Legal Proceedings</u>	24
Item 4. <u>Mine Safety Disclosures</u>	24
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	25
Item 6. <u>Selected Financial Data</u>	26
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
Item 8. <u>Consolidated Financial Statements and Supplementary Data</u>	F-1
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	35
Item 9A. <u>Controls and Procedures</u>	35
Item 9B. <u>Other Information</u>	35
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	36
Item 11. <u>Executive Compensation</u>	41
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters</u>	45
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	47
Item 14. <u>Principal Accountant Fees and Services</u>	49
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	51

**Table of Contents**

**Important Information Regarding Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements that relate to anticipated future events, future results of operations or future financial performance. These forward-looking statements include, but are not limited to, statements relating to our ability to raise sufficient capital to finance our planned operations, market acceptance of our technology and product offerings, our ability to attract and retain key personnel, our ability to protect our intellectual property, and our ability to develop commercially viable products with our technology. In some cases, you can identify forward looking statements by terminology such as may, might, will, should, intends, expects, plans, go forward with, projects, anticipates, assumes, believes, estimates, predicts, potential, or continue or the negative of these terms or other comparable terminology.

These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our (or our industry's) actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. The Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations sections of this Annual Report set forth detailed risks, uncertainties and cautionary statements regarding our business and these forward-looking statements.

We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future.

Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

## Table of Contents

### PART I

#### Item 1. Business.

##### Overview

We have developed and are commercializing a platform technology for the generation of functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by creation of constructs in 3D that have the potential to replicate native human biology. We can improve on previous technologies by moving away from monolayer 2D cell cultures and by enabling all or part of the tissues we create to be constructed solely of cells. We believe our demonstrated expertise in printing various fully cellular human tissues as disclosed in peer-reviewed scientific publications provides a strong foundation upon which other tissues can be built to replicate human biology and human disease. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, combined with strengths in engineering and biology, put us in an ideal position to provide a wide array of products for use in research, drug discovery and regenerative medicine therapies.

Our foundational proprietary technology derives from research led by Dr. Gabor Forgacs, the George H. Vineyard Professor of Biological Physics at the University of Missouri. We have a broad portfolio of intellectual property rights covering principles, enabling instrumentation applications and methods of cell based printing, including exclusive licenses to certain patented and patent pending technologies from the University of Missouri-Columbia, Clemson University, and Becton Dickinson and Company, and outright ownership of six pending patent applications (the patents and patent rights described in this paragraph are sometimes collectively referred to as the **Intellectual Property Rights** ). See **Intellectual Property** . We believe that our portfolio of Intellectual Property Rights provides a strong and defensible market position for our commercialization of 3D bioprinting technology.

We believe we have the potential to build and maintain a sustainable business by leveraging our core technology platform across a variety of applications. We have entered into multiple collaborative research agreements with pharmaceutical corporations. We have also secured five federal grants in the aggregate amount of approximately \$955,000, including Small Business Innovation Research grants to support the development of our technology. The Company developed the NovoGen MMX Bioprinter (our first-generation 3D bioprinter) within two and one half years of commencing operations. We were selected by MIT's Technology Review magazine among the Most Innovative Companies of 2012. We believe these corporate achievements provide strong validation for the commercial viability of our technology.

##### The Technology

Our technology is centered around multiple 3D bioprinting technologies utilizing our bioprinting instrument, the NovoGen MMX Bioprinter . Our 3D bioprinting technologies enables a wide array of tissue compositions and architectures to be created, using combinations of cellular bio-ink (building blocks comprised solely of cells), hydrogel (building blocks comprised of biocompatible gels), or hybrid bio-ink (building blocks comprised of a mixture of cells and material such as hydrogel). A key distinguishing feature of our bioprinting platform is the ability to generate three-dimensional constructs that have all or some of their components comprised entirely of cells. The fully-cellular feature of our technology enables architecturally and compositionally defined functional human tissues to be generated for *in vitro* use in drug discovery and development to potentially replicate the functional biology of native human tissue. Furthermore, fully cellular constructs may offer specific advantages for regenerative medicine applications where bioactive cells are required and three-dimensional configuration is necessary, such as augmenting or replacing functional mass in tissues and organs that have sustained acute or chronic damage.

## **Table of Contents**

We intend to deliver the following products to the market:

Three-dimensional models of human tissue for utilization in traditional absorption, distribution, metabolism, excretion (ADME) / toxicology (TOX) / and drug metabolism and pharmacokinetics (DMPK) testing in drug development.

Specific models of human biology or pathophysiology, in the form of three-dimensional human tissues, for use in drug discovery and development.

Three-dimensional human tissues for use as therapeutic regenerative medicine products, such as blood vessels for bypass grafting, nerve grafts for nerve damage repair and regenerative patches for treatment of heart disease.

3D bioprinters for use in medical research.

A portfolio of consumables for use with our 3D bioprinters.

We have entered into collaborations with multiple corporate and academic partners that we believe provide validation of the value of our 3D bioprinting technology.

## **Market Opportunity**

We believe that our bioprinting technology is uniquely positioned to provide functional human tissues for use in drug discovery and development as well as a broad array of tissues suitable for therapeutic use in regenerative medicine applications. While there are rapid-prototyping printers currently available that build three dimensional structures out of polymers (often used for prototyping of plastic parts for tools or devices), these instruments are not specifically designed or intended for use with purely cellular inks in building biologic tissues and we do not believe that the firms working on these instruments have the required biology expertise to create tissues using these instruments.

There are multiple addressable markets for our technology platform:

- 1) **Specialized Models for Drug Discovery and Development:** The NovoGen MMX Bioprinter can produce highly specialized functional human tissues that can be utilized to model a specific tissue physiology or pathophysiology. Our bioprinting technology has demonstrated the ability to create human blood vessel constructs, and to create fully human tissue containing microvascular structures. These capabilities are anticipated to broaden the scope and scale of 3D tissues that can be generated, and to facilitate the development of disease models in such areas as cardiovascular disease, oncology, and fibrosis.
- 2) **Biological Research Tools:** Absorption, distribution, metabolism, excretion (ADME) testing is used to determine which factors enhance or inhibit how a potential drug compound reaches the blood stream. Distribution of a compound can be affected by binding to plasma proteins; age, genetics, and other factors can influence metabolism of a compound; and the presence of certain disease states can have effects on excretion of a compound. Many companies perform ADME studies utilizing various cell-based assays or automated bioanalytical techniques. Drug metabolism and pharmacokinetics (DMPK) testing is a subset of ADME. Determining the DMPK properties of a drug helps the drug developer to understand its safety and efficacy. Toxicology (TOX) testing is a further requirement to determine the detrimental effects of a particular drug on specific tissues. We believe that the NovoGen MMX Bioprinter is positioned to deliver highly differentiated products for use in traditional cell-based ADME / TOX / DMPK studies. Products in this arena may replace or complement traditional cell based assays that typically employ primary hepatocytes, intestinal cell lines, renal epithelial cells and cell lines grown in a traditional two-dimensional format. Importantly, the combination of tissue-like three-dimensionality and human cellular components is believed to provide an advantage over non-human animal systems toward predicting *in vivo* human outcomes.

- 3) Regenerative Medicine: The field of regenerative medicine is advancing via multiple strategic approaches in development and practice, including cell therapies and scaffold-based products

## **Table of Contents**

(+/- cells). The architectural precision and flexibility of our technology may facilitate the optimization, development, and clinical use of three-dimensional tissue constructs. Importantly, our technology offers a next-generation strategy whereby three-dimensional structures can be generated without the use of scaffolding or biomaterial components. The ultimate goal is to enable fully cellular constructs to be generated in a configuration compatible with surgical modes of delivery, thereby enabling restoration of significant functional mass to a damaged tissue or organ.

We believe that our technology can capitalize, via strategic partnerships, on additional market opportunities in the provision of enabling tools for drug discovery and development as well as the discovery and development of therapeutic implants that augment or replace damaged tissues and organs. We believe there are multiple short- and long-term revenue opportunities for us in these areas, including direct sales of 3D human tissue constructs for drug screening and development, licensing fees for commercial access to our technology, and royalties from product enablement, particularly in the area of therapeutic products for regenerative medicine.

## **Background on Bioprinting**

The formation of bio-ink, the cell-based building blocks that can be dispensed by our bioprinter, relies on the demonstrated principle that groups of individual cells will self-assemble to generate aggregates, through the actions of cell surface proteins that bind to each other and form junctions between cells. Furthermore, if two or more compatible self-assembled aggregates are placed in close proximity, under the proper conditions they will fuse to generate larger, more complex structures via physical properties analogous to those that drive fusion of liquid droplets. The concept of tissue liquidity originated in studies of developmental biology, where it was noted that developing tissues have liquid-like properties that enable individual cellular components to pattern each other, migrate, organize, and differentiate. As development progresses, tissues transition from a dynamic viscous liquid state to a more static semi-solid state, largely driven by the compartmentalized organization of cellular components and production within the organized tissue of extracellular matrix proteins that provide the mature tissue with the biomechanical properties required for tissue specific function.

Figure 1 demonstrates self-assembly and tissue liquidity using cellular aggregates generated from developing chicken heart tissue, showing that two adjacent aggregates will fuse over time and generate a larger cellular structure. This basic behavior can be leveraged to form more complex structures whereby aggregates are arranged in a specific geometry that can recapitulate shapes and architectures commonly found in tissues and organs, including tubes and multi-layered structures.



## **Table of Contents**

**Figure 1.** Developing cardiac tissue was harvested and utilized to generate cellular aggregates which were placed into culture adjacent to each other. Over a period of about 24 hours, the aggregates merge and fuse into a single unified structure. Scale bar = 100mm. *Adapted from Tissue Engineering Part A , 14(3):413m 2008, co-authored by Gabor Forgacs.*

Figure 2 shows that the phenomenon of aggregate fusion in embryonic tissue can be extended to adult-derived cultured mammalian cells, as demonstrated by the fusion of adult hamster ovary epithelial cell aggregates to form toroid (ring) structures when placed into that geometry and held for about 120 hours.

**Figure 2.** Cultured Chinese Hamster Ovary (CHO) cells were used to make 12 spherical cell aggregates, which were printed as a ring structure in a biocompatible hydrogel. Structure is shown immediately after printing (left) and at 120 hours (right). *Adapted from the Journal of Materials Chemistry 17:2054, 2007, co-authored by Gabor Forgacs.*

### *THE NOVOGEN MMX BIOPRINTER*

Our NovoGen MMX Bioprinter is an automated device that enables the fabrication of three-dimensional (3D) living tissues comprised of mammalian cells. A custom graphic user interface (GUI) facilitates the 3D design and execution of scripts that direct precision movement of the dispensing heads to deposit cellular building blocks ( bio-ink ) or supporting hydrogel. The unit fits easily into a standard biosafety cabinet, eliminating the need to purchase ancillary equipment or make facility modifications to maintain sterility of bioprinted tissues during the printing process. The speed and precision of this instrument enables the production of small-scale tissue models for *in vitro* use in drug discovery and development.

The NovoGen MMX Bioprinter (Figure 3) went from in-licensing and initial design to commercial production in less than two years. It is manufactured for us by Invetech Pty., of Melbourne, Australia.

**Figure 3.** The NovoGen MMX Bioprinter has a footprint that enables it to fit into a standard biosafety cabinet. Features of the first-generation instrument include two dispensing heads, temperature control, automatic calibration, and a custom software interface for integrated experimental design and instrument control.

## **Table of Contents**

The first step in bioprinting is preparation of the bio-ink aggregates, which are typically generated in spherical or cylindrical format. Bio-ink can be generated from a wide variety of cell types, including cell lines, primary cells, stromal cells, epithelial cells, endothelial cells, and progenitor cells. Once formed, the bio-ink building blocks are loaded into the bioprinter, which then dispenses them layer by layer in the geometry specified by the user, with a bio-inert hydrogel serving as a physical support for the bioprinted tissue as well as occupying any negative space included in the design.

The NovoGen MMX Bioprinter has proved to be a powerful enabling tool for the design, optimization, and fabrication of viable functional human tissues, based on our internal product discovery and development efforts as well as the experience of our corporate partners and customers. Continuing use of the NovoGen MMX Bioprinter in the pursuit of multiple drug discovery and therapeutic applications has provided key insights that will be utilized in the evolution of the bioprinter platform. We believe that purpose-driven improvements and added product features, combined with new capabilities enabled by additional in-licensed intellectual property, will enhance our ability to deliver commercially viable outputs for corporate partners in drug development and implantable therapeutics.

The NovoGen MMX Bioprinter has won the following awards and accolades:

2010 International Society for Biofabrication Meeting - Special Award

2010 TIME Magazine 50 Best Inventions of 2010

2011 Australian Engineering Innovation Award, sponsored by the Australian government

In 2011 and 2012 we provided NovoGen MMX Bioprinters for use by the following institutions, among others, for research purposes: Harvard Medical School, Wake Forest University, and the Sanford Consortium for Regenerative Medicine ( SCRM ). The SCRM is a new institution which opened in November, 2011, comprised of faculty from the Salk Institute, The Scripps Research Institute, the University of California, San Diego, Sanford-Burnham Medical Research Institute, and La Jolla Allergy and Immunology Institute. We believe that the use of our bioprinting platform by major research institutions will increase the understanding of the technological and research value of the platform, ultimately creating future opportunities for intellectual property licensing.

## **Table of Contents**

### ***SPECIFIC APPLICATIONS FOR FUNCTIONAL HUMAN TISSUES***

Our bioprinting technology and surrounding intellectual property and commercial rights serve as a platform for product generation across multiple markets that employ cell- and tissue-based products and services. The core capability of our technology is the production of human tissues with the potential to recapitulate human biology. Once generated, these *in vivo*- like human tissues may be suitable for a variety of applications such as research tools, specialized models of tissue pathobiology, and implantable therapeutics for tissue engineering and regenerative medicine (Figure 4). Importantly, the basic fabrication and maturation protocols that generate functional micro-scale tissues for *in vitro* use will serve as a foundation for the design and manufacture of larger-scale tissues intended for therapeutic use to augment or replace damaged or degenerating organs.

### **Collaborative Agreements**

In December, 2010 we entered into a Collaborative Research Agreement with Pfizer, Inc. ( **Pfizer** ) to develop tissue based drug discovery assays in two therapeutic areas utilizing our NovoGen MMX Bioprinter technology. We disclosed in 2012 that we had delivered constructs to Pfizer for internal evaluation as partial completion of the collaboration agreement; we additionally have delivered a study report to complete the scope of work in the original collaboration agreement. Constructs delivered by Organovo are currently being evaluated in the collaborator's laboratory, and we anticipate that an additional agreement or agreements will be arrived at to utilize Organovo tissues in its future research efforts, although we can give no assurance that future agreements will be arrived at.

In October 2011, we entered into a Research Agreement with United Therapeutics Corporation ( **Unither** ) to establish and conduct a research program to discover treatments for pulmonary hypertension using our NovoGen MMX Bioprinter technology, which remains in effect until the later of 30 months from its commencement or our completion of the contracted research. We have progressed the work on this agreement according to the research plan. In November 2012 we executed an additional agreement with United Therapeutics describing additional research scope and providing for additional collaborative research funding, in an expansion of the original agreement from October 2011.

## **Table of Contents**

In January 2013, we entered into a collaboration agreement with the Knight Cancer Institute at Oregon Health & Science University, a national leader in translational oncology research, to develop more clinically predictive in vitro three dimensional cancer models which are ultimately expected to advance discovery of novel cancer therapeutics.

### **Competition**

We are subject to significant competition from pharmaceutical, biotechnology, and diagnostic companies; academic and research institutions; and government or other publicly-funded agencies that are pursuing the development of research tools and therapeutic products that otherwise address the needs of our potential customers. We believe our future success will depend, in large part, on our ability to maintain a competitive position in our field. Biopharmaceutical technologies have undergone and are expected to continue to undergo rapid and significant change. We or our competitors may make rapid technological developments which may cause our research tools or therapeutic products to become obsolete before we recover the expenses incurred. The introduction of less expensive or more effective therapeutic discovery and development technologies, including technologies that may be unrelated to our field, may also make our technology less valuable or obsolete. We may not be able to make the necessary enhancements to our technologies or research tools to compete successfully with newly emerging technologies. The failure to maintain a competitive position in the biopharmaceutical field may result in decreased revenues.

We are a platform technology company dedicated to the development and production of functional human tissues that service both the drug development and regenerative medicine industries. To our knowledge, there are no other companies with a similar pure play focus on this platform technology or marketed products.

Set forth below is a discussion of competitive factors for each of the broad markets in which we intend to utilize our technology:

**Highly Specialized Models for Drug Discovery:** This aspect of our business is driven by leveraging our technology as a high-end partnered service that enables a customer to discover or optimally formulate a pharmacologic product that delivers a specific therapeutic effect, or avoids a particular side effect. In addition to revenue generated from the tissue production work, additional revenues are possible in the form of up-front license fees, milestone payments, know-how payments, and royalties. We can provide the customer access to tissues as a service or can produce and supply the tissues to customers; both options are designed to generate continuing revenue. Competition in this area arises mainly from two sources, traditional cell-based *in vitro* culture approaches and traditional *in vivo* animal models and testing.

We believe that an important factor distinguishing our approach from that of our competitors is our ability to build models that are composed of human cells and have a 3D tissue-like configuration (i.e., able to generate results that are not subject to inherent limitations of 2D monolayer culture). We acknowledge, however, that there are some areas of research for which the existing methods (2D cell culture and/or animal studies) are adequate and 3D *in vitro* human tissues are not sufficiently advantageous.

**Tools for Research and Drug Development:** We intend to employ our technology to provide an array of broadly-applicable enabling tools and assays to the drug research markets. Examples of products in this segment of the business include future pipeline efforts in the development of the NovoGen MMX Bioprinter instrument and human tissue models that service the ADME/TOX/DMPK markets as alternatives or supplements to traditional cell-based assays and animal studies.

Competition in the bioprinter arena has been limited to date. We believe that we have a first to market advantage in being the first and only company to leverage a purely cellular bioprinting system commercially, which does not rely on the presence of foreign, non-native polymer in the final tissue constructs. Some academic groups have internally created inkjet bioprinting systems, but these systems have not been developed commercially to date.

## Table of Contents

and are unlikely to be as effective in the generation of larger-scale 3D tissues. Furthermore, commercialization of certain inkjet based technologies will require certain intellectual property rights.

**Regenerative Medicine:** This aspect of our business involves application of our 3D bioprinting technology to generate human tissues suitable for implantation *in vivo* to augment or replace damaged or degenerating tissues. The majority of these efforts will be undertaken as partnered projects with leading therapeutic companies seeking to develop a tissue engineering / regenerative medicine product for a specific application, or developed by us alone. Near-term revenues would come from the funding of development work and, in some cases, licensing fees for access to our platform technologies. We expect longer-term revenues may arise from shared profits and royalties or other forms of income from successful clinical and commercial development of the tissue products. There are many companies pursuing the discovery, development, and commercialization of tissue-engineered products for a variety of applications, including but not limited to Organogenesis, Advanced BioHealing (recently acquired by Shire), Tengion, Genzyme (a subsidiary of Sanofi), HumaCyte and Cytograft Tissue Engineering. These companies uniquely represent potential competition for us while also being candidates for potential partners. For any tissue-engineered / regenerative medicine product where three-dimensionality is desired, our platform has a unique ability to enable generation of prototypes, optimization of prototypes and protocols, and production of the tissue.

## **Intellectual Property**

Our success depends in large part on our ability to obtain and enforce patents, maintain protection of trade secrets and operate without infringing the proprietary rights of third parties. We hold exclusive licenses to four U.S. patents, three U.S. patent applications and multiple corresponding international patent applications. We have filed seven U.S. patent applications and corresponding international patent applications regarding our technology and its various uses in areas of tissue creation and utilization in drug discovery, including filings for specific tissue types.

In March, 2009, we obtained a world-wide exclusive license to a suite of intellectual property owned by the University of Missouri-Columbia ( **MU** ) and the Medical University of South Carolina covering two patents:

Self-Assembling Cell Aggregates and Methods of Making Engineered Tissue Using the Same US 10/590,446 and 8,241,905.

Self-Assembling Multicellular Bodies and Methods of Producing a Three-Dimensional Biological Structure Using the Same PCT/US 2009/48 and US 8,143,055.

In addition, in March, 2010 we licensed additional intellectual property from MU covering the composition and method of manufacture of a nerve conduit. Dr. Gabor Forgacs, is one of our Founders and the unique inventor of all of these works (the **Forgacs Intellectual Property** ). The Forgacs Intellectual Property provides us with intellectual property rights to create cellular aggregates, to use cellular aggregates to create engineered tissue, and to employ cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen MMX Bioprinter to create engineered tissues, and provides us with rights to specific compositions with utility in the creation of nerve conduit.

The Forgacs Intellectual Property is the result of years of research by Dr. Gabor Forgacs, the George H. Vineyard Professor of Biophysics at the University of Missouri-Columbia and his collaborators and research teams. Dr. Forgacs is a sought after expert in biofabrication with a long record of peer-reviewed publications. The Forgacs Intellectual Property derives from work done in the labs of Dr. Forgacs and his collaborators, including the work done under a \$5,000,000 Frontiers in Biological Research grant that Dr. Forgacs and his collaborators received from the National Science Foundation.

In March 2012, the U.S. Patent and Trademark Office issued a patent (US 8,143,055) for the patent application titled Self-Assembling Multicellular Bodies and Methods of Producing a Three-Dimensional Biological

## **Table of Contents**

Structure Using the Same. The patent provides us with intellectual property rights to create cellular aggregates, to use cellular aggregates to create engineered tissue, and to employ cellular aggregates to create engineered tissue with no scaffold present.

In August 2012, the U.S. Patent and Trademark Office issued a patent (US 8,241,905) for the patent application titled Self-Assembling Cell Aggregates and Methods of Making Engineered Tissue Using the Same. The patent provides us with intellectual property rights in the creation of engineered tissue. Under its agreements with the University of Missouri, we hold the exclusive license to these issued patents (US 8,143,055 and US 8,241,905) and future continuation patents derived from the same applications.

In May 2012, the Intellectual Property Office of the United Kingdom issued us a patent GB2478801, entitled Multilayered Vascular Tubes. This is our first issued patent and represents the issuance of a patent from our first patent application, which was submitted in May 2010. The original patent application continues to be under review at the U.S. Patent and Trademark Office and multiple other jurisdictions. In November 2012, Hong Kong patent HK1159682 was issued to us similar matter. In February 2013, additional claims from this patent were issued in the United Kingdom as patent GB2489081.

In May, 2011, we obtained an exclusive license to a patent entitled Ink Jet Printing of Viable Cells (US 7,051,654) from the Clemson University Research Foundation ( **CURF Patent** ). The CURF Patent provides us with the intellectual property rights to methods of using ink-jet printer technology to dispense cells, and to create matrices of bioprinted cells on gel materials.

In February of 2013, we purchased the exclusive rights to Perfusion Bioreactors for Culturing Cells (US 7,767,446 and related foreign patents) from Becton Dickinson and Company. This patent represents the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development. No future royalties or milestone payments are owed to Becton Dickinson and Company for this patent.

Under our license arrangements, we have the right to sublicense the Forgacs Intellectual Property and the CURF Patent. We have full control and authority over the development and commercialization of any licensed products, including clinical trials, manufacturing, marketing, and regulatory filings. We were required to submit and have submitted plans for commercialization of all technologies and are required to make efforts to pursue commercial development of the technology. We are required to make payments on an annual basis after commercialization to maintain the license rights.

Further, we will be required to make pass through payments for sublicenses of the Forgacs Intellectual Property and the CURF Patent based on license fees or royalty payments received. In addition, following commercialization, we are required to make ongoing royalty payments equal to a low single digit percentage of net sales of the licensed products.

We currently have U.S. patent applications pending to protect our proprietary methods processes and compositions and have also filed, and intend to file, corresponding foreign patent applications. We believe that protection of the proprietary nature of our products and technologies is essential to our business. Accordingly, we have adopted and will continue a vigorous program to secure and maintain protection of our intellectual property. We file patent applications with respect to novel technology, and improvements thereof that are important to our business. We also rely upon trade secrets, unpatented know-how, continuing technological innovation and the pursuit of licensing opportunities to develop and maintain our competitive position. There can be no assurance that others will not independently develop substantially equivalent proprietary technology or that we can meaningfully protect our proprietary position.

## **Regulatory Considerations**

We are not aware of any current FDA regulatory requirements for sales or use of research tools, such as bioprinters into a research setting. All human cells utilized in our research and, ultimately in our bioprinted tissue

## **Table of Contents**

products, are collected in compliance with the FDA's guidance for Current Good Tissue Practices (CGTP). However, pharmaceutical industry corporate customers with whom we will enter into partnerships will face regulatory review of the research data they generate using our platform and research tools. Good Laboratory Practice (GLP) data is required in the development of any human therapeutic, and our platform has been designed to support compliance with GLP, although no independent certification has been performed to date to confirm this compliance. All product contact surfaces are sterilizable or disposable. GLP considerations around areas such as data integrity are the sole responsibility of the customer without regard to specifics of the research tool used.

Therapeutic tissues and other regenerative medicine products are subject to an extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and human studies is lengthy and expensive. The resource investment necessary to meet the requirements of these regulations will fall on our collaborating partners, or may be shared with us, to the extent that we are developing proprietary products that are the result of a collaboration effort. The resource investment of time, staff and expense to satisfy these regulations will fall on us to the extent we are developing proprietary products on our own. We may not be able to obtain FDA approvals for those products in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technology and have not been the subject of extensive product testing in humans. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by foreign governmental regulatory authorities that could prevent or delay approval in those countries. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

As constructs move into clinical and commercial settings, full compliance with the FDA's CGTP (Current Good Tissue Practices) and CGMP (Current Good Manufacturing Practices) guidelines will be required. Suitable design and documentation for clinical use of the bioprinter will be a part of future phases of printer design programs.

## **Employees**

We currently have thirty-seven employees, of whom twenty-nine are employed full time. We also engage consultants and temporary employees from time to time to provide services that relate to our bioprinting business and technology as well as for general administrative and accounting services.

## **Available Information**

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the **Exchange Act**). Reports filed with the SEC pursuant to the Exchange Act, including annual and quarterly reports, and other reports we file, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. Investors may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. Investors can request copies of these documents upon payment of a duplicating fee by writing to the SEC. The reports we file with the SEC are also available on the SEC's website (<http://www.sec.gov>).

## **Table of Contents**

### **Item 1A. Risk Factors.**

*Investment in our common stock involves a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our common stock should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our common stock, you should carefully consider the risk and uncertainties described below in addition to the other information incorporated herein by reference. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. In any case, the trading price of our common stock could decline, and you could lose all or part of your investment.*

#### **Risks related to our Business and our Industry**

*We have a limited operating history and a history of operating losses, and expect to incur significant additional operating losses.*

We were incorporated in 2007, opened our laboratories in San Diego, California in January, 2009 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses since we began operations, including \$9.3 million and \$2.3 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had incurred cumulative operating losses of \$13.7 million and cumulative net losses totaling \$50.2 million. We expect to incur substantial additional operating losses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, entering into customer relationships with strategic partners, successful completion of the preclinical and clinical development of our partners' product candidates; obtaining necessary regulatory approvals by our partners or us from the FDA and international regulatory agencies; successful manufacturing, sales, and marketing arrangements; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

*We will need to secure additional financing to support our planned operations.*

We will require additional funds for our anticipated operations and if we are not successful in securing additional financing, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products.

*We are an early-stage company with an unproven business strategy and may never achieve commercialization of our research tools and therapeutic products or profitability.*

Our strategy of using our research tools for the collaborative development of therapeutic products is unproven. Our success will depend upon our ability to enter into additional collaboration agreements on favorable terms, to determine which research tools and therapeutic products have potential value, and to select an appropriate commercialization strategy for each research tool and potential therapeutic product we or our collaborators choose to pursue. If we are not successful in implementing our strategy to commercialize our research tools and potential therapeutic products, we may never achieve, maintain or increase profitability.

*Our success and our collaborators' ability to sell therapeutic products will depend to a large extent upon reimbursement from health care insurance companies.*

Our success may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities,



## **Table of Contents**

private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us or our collaborative partners to establish and maintain price levels that are sufficient for realization of an appropriate return on investment in product development.

### ***Our research tools are new and unproven and may not allow us or our collaborators to develop successful commercial products***

Our research tools involve new and unproven approaches. We have not proven that our research tools will enable us or our collaborators to identify therapeutic products with commercial potential, or to develop or commercialize such therapeutic products. Even if we or our collaborators are successful in identifying therapeutic products based on discoveries made using our research tools, we or our collaborators may not be able to discover or develop commercially viable products. To date, no one has developed or commercialized any therapeutic or other life science product based on our research tools. If our research tools do not assist in the discovery and development of such therapeutic products, our current and potential collaborators may lose confidence in us and our research tools and our business may suffer as a result.

If our collaborators, licensees and customers do not successfully develop or commercialize therapeutic or other life science products using our research tools, we may not generate revenues from those customers. In addition, we may experience unforeseen technical complications, unrecognized defects and limitations in the productions of our research tools. These complications could materially delay or limit the use of those tools, substantially increase the anticipated cost of manufacturing them or prevent us from implementing research projects at high efficiency levels.

### ***Our products and services are subject to the risks associated with new and rapidly evolving technologies.***

Our proprietary tissue creation technology, drug discovery and research tools are subject to the risks associated with new, rapidly evolving technologies. In addition, the process of developing new technologies and products is complex, and if we are unable to develop enhancements to, and new features for, our existing products or acceptable new products that keep pace with technological developments or industry standards, our products may become obsolete, less marketable and less competitive.

### ***The commercialization of therapeutic or other life science products developed using our research tools is subject to a variety of risks.***

Development of therapeutic and other life science products based on our or our collaborators' use of our technologies will be subject to risks of failure inherent in their development or commercial viability. These risks include the possibility that any such products will:

fail to be found through the use of research tools;

be found to be toxic;

be found to be ineffective;

fail to receive necessary regulatory approvals;

be difficult or impossible to manufacture on a large scale;

be economically infeasible to market;



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**Table of Contents**

fail to be developed prior to the successful marketing of similar products by competitors; or

be impossible to market because they infringe the proprietary rights of third parties or compete with superior products marketed by third parties.

We expect that our drug discovery collaborative partners or other clients that utilize our research tools will be required to submit their research for regulatory review in order to proceed with human testing of drug candidates. This review by the FDA and other regulatory agencies may result in timeline setbacks or complete rejection of an application to begin human studies, such as an Investigative New Drug (IND) application. Should our collaborative partners or other clients face such setbacks, we would be at risk of not being paid if there were agreed upon milestone and royalty payments. The risks of non-approval for our partners or other clients will include the inherent risks of unfavorable regulator opinion of a drug candidate's safety or efficacy, as well as the risk that the data generated by our platform technology is not found to be suitable to support the safety or efficacy of the drug. In addition, our platform technology is subject to the requirements of Good Laboratory Practice (GLP) to provide suitable data for INDs and other regulatory filings; no regulatory review of data from this platform has yet been conducted and there is no guarantee that our technology will be acceptable under GLP.

***If we are unable to enter into or maintain strategic collaborations with third parties, we may have difficulty selling our research tools and therapeutic products and we may not generate sufficient revenue to achieve or maintain profitability.***

Since we do not currently possess the resources necessary to develop, obtain approvals for or commercialize potential therapeutic products based on our technology, we must enter into collaborative arrangements to develop and commercialize these products. If we are not able to enter into these arrangements or implement our strategy to develop and commercialize therapeutic and other life science products based upon our research tools, we may not generate sufficient revenues to achieve or maintain profitability. Additionally, we may not be able to negotiate future collaborative arrangements on acceptable terms, if at all.

***We cannot control our collaborators' allocation of resources or the amount of time that our collaborators devote to developing our programs or potential products, which may have a material adverse effect on our business.***

Our agreements with our collaborators typically allow them significant discretion in electing whether to pursue product development, regulatory approval, manufacturing and marketing of the products they may develop with the help of our technology. We cannot control the amount and timing of resources our collaborators may devote to our programs or potential products. As a result, we cannot be certain that our collaborators will choose to develop and commercialize these products or that we will realize any milestone payments, royalties and other payments to which we may become entitled. In addition, if a partner is involved in a business combination, such as a merger or acquisition, or if a partner changes its business focus, its performance pursuant to its agreement with us may suffer and, as a result, we may not generate any revenues from royalty, milestone and similar provisions that may be included in our collaborative agreement with that partner.

***Any termination or breach by or conflict with our collaborators or licensees could harm our business.***

If we or any of our collaborators or licensees fail to renew or terminate any of our collaboration or license agreements or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could lose significant sources of revenue, which could result in volatility in our future revenue.

In addition, our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to

## **Table of Contents**

termination of the agreement or delays in collaborative research, development, supply or commercialization of certain products, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to our intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations or license agreements may prove to be unsuccessful.

***Our collaborators could develop competing research, reducing the available pool of potential collaborators and increasing competition, which may adversely affect our business and revenues.***

Our collaborators and potential collaborators could develop research tools similar to our own, reducing our pool of possible collaborative parties and increasing competition. Any of these developments could harm our product and technology development efforts, which could seriously harm our business. In addition, we may pursue opportunities in fields that could conflict with those of our collaborators. Developing products that compete with our collaborators or potential collaborators products could preclude us from entering into future collaborations with our collaborators or potential collaborators. Any of these developments could harm our product development efforts and could adversely affect our business and revenues.

***If restrictions on reimbursements and health care reform limit our collaborators actual or potential financial returns on therapeutic products that they develop based on our platform technology, our collaborators may reduce or terminate their collaborations with us.***

Our collaborators abilities to commercialize therapeutic and other life science products that are developed through the research tools or services that we provide may depend in part on the extent to which coverage and adequate payments for these products will be available from government payors, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payors. These payors are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved therapeutic and other life science products, and coverage and adequate payments may not be available for these products.

In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals included measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of pharmaceuticals and other medical products to government control. Government and other third-party payors increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the FDA has granted marketing approval. Governments may adopt future legislative proposals and federal, state or private payors for healthcare goods and services may take action to limit their payments for goods and services. Any of these events could limit our ability to form collaborations or collaborators and our ability to commercialize therapeutic products successfully.

***We and our collaborators are subject to extensive and uncertain regulatory requirements, which could adversely affect our ability to obtain regulatory approval in a timely manner, or at all, for products that we identify or develop.***

Therapeutic and other life science products are subject to an extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and human studies is lengthy and expensive. The burden of these regulations will fall on our collaborating partners, or may be shared with us, to the extent that we are developing proprietary products that are the result of a collaboration effort. The burden of these regulations will fall on us to the extent we are developing proprietary products on our own.

## **Table of Contents**

We may not be able to obtain FDA approvals for those products in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technology and have not been the subject of extensive product testing in humans. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by foreign governmental regulatory authorities that could prevent or delay approval in those countries. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

### ***Our business depends upon the success of our research tools as alternatives to current research tools.***

Our success depends on commercial acceptance of our research tools. We believe that adoption of our research tools by our current and future collaborators will be essential for commercial acceptance of our research tools. We cannot assure you that our research tools will be adopted, or if adopted, that they will be broadly accepted by pharmaceutical, biotechnology and diagnostic companies or various academic institutions.

We believe that recommendations by health care professionals and health care payors will be essential for commercial acceptance of our collaborators' or our products. We cannot assure you that the products we or our collaborators develop will achieve commercial acceptance among patients, physicians or third-party payors. Our inability to achieve commercial acceptance would materially adversely affect our business, financial condition and results of operations.

### ***We face intense competition which could result in reduced acceptance and demand for our research tools and products.***

The biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources, experience and expertise in research and development, preclinical testing, designing and implementing clinical trials; regulatory processes and approvals; production and manufacturing; and sales and marketing of approved products than we have experienced to date. Principal competitive factors in our industry include the quality and breadth of technology; management and the execution of strategy; skill and experience of employees, ability to recruit and retain skilled, experienced employees; intellectual property portfolio; the range of capabilities, including target identification, validation, drug and device discovery, development, manufacturing, marketing; and the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies compete in the biotech market. In particular, these companies have greater experience and expertise than we have in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products than we have currently.

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established biotech or other companies, or the obtaining of substantial private financing. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we or our collaborators will be successful in commercializing and gaining significant market share for any

## **Table of Contents**

products developed in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by our competitors.

*We may have product liability exposure from the sale of our research tools and therapeutic products or the services we provide.*

We may have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. Given our operations to date, we currently do not maintain any product liability insurance coverage. At such point that we determine it is prudent to obtain this insurance, we may not be able to obtain or maintain insurance at a reasonable cost. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

*The near and long-term viability of our products and services will depend on our ability to successfully establish strategic relationships.*

The near and long-term viability of our products and services will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product or service candidates for several reasons both within and outside of our control.

Although our current focus is on providing drug discovery services and research tools in the research setting, we may develop tissue therapeutic products and seek approval to sell them as medical care. Before we could begin commercial manufacturing of any of our product candidates, we or our manufacturers must pass a pre-approval inspection by the FDA and comply with the FDA's current Good Manufacturing Practices. If our manufacturers fail to comply with these requirements, our product candidates would not be approved. If our collaborators fail to comply with these requirements after approval, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell products.

*We will be dependent on third-party research organizations to conduct some of our future laboratory testing, animal and human studies.*

We will be dependent on third-party research organizations to conduct some of our laboratory testing, animal and human studies with respect to therapeutic tissues and other life science products that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with

## **Table of Contents**

regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our future product candidates.

### ***We may require access to a constant, steady, reliable supply of products.***

To the extent that we develop products for sale, we may be required to complete clinical trials before we can offer such products for sale. Commercialization of products will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. If we are unable to manufacture our products in commercial quantities, then we will need to rely on third parties. These third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. In addition, we may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. Furthermore, we would likely have to enter into a technical transfer agreement and share our know-how with the third party manufacturer.

### ***We may rely on third-party suppliers for some our materials.***

We may rely on third-party suppliers and vendors for some of the materials we require in our drug discovery and research tool businesses as well as for the manufacture of any product candidates that we may develop in the future. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

### ***Violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.***

To the extent that our collaborators or customers use our products in the manufacturing or testing processes for their drug and medical device products, such end-products or services may be regulated by the FDA under Quality System Regulations (QSR) or the Centers for Medicare & Medicaid Services (CMS) under Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations. The customer is ultimately responsible for QSR, CLIA '88 and other compliance requirements for their products; however, we may agree to comply with certain requirements, and, if we fail to do so, we could lose sales and customers and be exposed to product liability claims.

Products that are intended for the diagnosis or treatment of disease are subject to government regulation. Our drug discovery and research tool offerings are currently intended for research or investigational uses. Research uses are not subject to FDA or premarket approval or other regulatory requirements. Investigational uses are not subject to FDA premarket approval or most regulatory requirements, but are subject to limited regulatory controls for entities conducting investigational studies.

As we continue to adapt and develop parts of our product line in the future, including tissue-based products in the field of regenerative medicine, the manufacture and marketing of our products will become subject to government regulation in the United States and other countries. In the United States and most foreign countries, we will be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

## **Table of Contents**

The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IDE (Investigational Device Exemption), NDA (New Drug Application), or BLA (Biologic License Application) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are outside of our control. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to our distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our product candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

### ***We are subject to various environmental, health and safety laws.***

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.



## **Table of Contents**

***We will depend on our patent portfolio, our licensed technology and other trade secrets in the conduct of our business and must ensure that we do not violate the patent or intellectual rights of others.***

Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we and our licensors must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and as to which we do not hold licenses or other rights. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic treatment candidate that is the subject of the suit.

In addition, competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement for unauthorized use. This can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent owned by us is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover our technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

***A significant portion of our sales are dependent upon our customers' capital spending policies and research and development budgets, and government funding of research and development programs at universities and other organizations, which are each subject to significant and unexpected decrease.***

Our prospective customers include pharmaceutical and biotechnology companies, academic institutions, government laboratories, and private research foundations. Fluctuations in the research and development budgets at these organizations could have a significant effect on the demand for our products and services. Research and development budgets fluctuate due to changes in available resources, patent expirations, mergers of pharmaceutical and biotechnology companies, spending priorities, general economic conditions, and institutional and governmental budgetary policies, including but not limited to reductions in grants for research by educational institutions. In addition, our business could be seriously damaged by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, academic institutions, government laboratories, or private foundations.

The timing and amount of revenues from customers that rely on government funding of research may vary significantly due to factors that can be difficult to forecast. Research funding for life science research has increased more slowly during the past several years compared to the previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to various institutions, sometimes without advance notice. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the United States government as a higher priority. These budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. Past proposals to reduce budget deficits have included reduced National Institute of Health and other research and development allocations. Any shift away from the funding of life sciences research and development or delays surrounding the approval of government budget

## **Table of Contents**

proposals may cause our customers to delay or forego purchases of our products or services, which could seriously damage our business.

### **Risks Related to Our Common Stock and Liquidity Risks**

*Our securities are a Penny Stock and subject to specific rules governing their sale to investors.*

The SEC has adopted Rule 15c-9 which establishes the definition of a penny stock, for the purposes relevant to our common stock, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information, investment experience and objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the penny stock rules. This may make it more difficult for investors sell shares of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

*The Company has a limited trading history and there is no assurance that an active market in the Company's common stock will continue at present levels or increase in the future.*

There is limited trading activity in our common stock and there is no assurance that an active market will develop in the future. Although our common stock is currently quoted on the OTCQX, the Company has a limited trading history and there is no assurance that an active market in the Company's common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock. There can be no assurance that a more active market for our common stock will develop in the future, or if one should develop, there is no assurance that it will be sustained. This factor limits the liquidity of our common stock, and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

*Compliance with the reporting requirements of federal securities laws can be expensive.*

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of the Registration Statement and related documents with respect to the registration of resales of the common stock underlying the Original Warrants.

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## **Table of Contents**

*Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of our common stock.*

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

*We may have undisclosed liabilities and any such liabilities could harm our revenues, business, prospects, financial condition and results of operations.*

Even though our pre-merger assets and liabilities were transferred to the Split-Off Shareholders in the Split-Off, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survived the Merger could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities. The transfer of the operating assets and liabilities to PSOS, coupled with the Split-Off of PSOS, will result in taxable income to us in an amount equal to the difference between the fair market value of the assets transferred and the pre-merger tax basis of the assets. Any gain recognized, to the extent not offset by our net operating loss carryforward, if any, will be subject to federal income tax at regular corporate income tax rates.

*If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.*

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement. We are in the process of implementing changes to internal controls, but have not yet completed implementing these changes. Failure to implement these changes to our internal controls or any others that it identifies as necessary to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our stock.

*The price of our common stock may continue to be volatile, which could lead to losses by investors and costly securities litigation.*

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the timing of IDE and/or NDA approval, the completion and/or results of our clinical trials;

regulatory actions regarding our products;

**Table of Contents**

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

adoption of new accounting standards affecting the our industry;

additions or departures of key personnel;

introduction of new products by us or our competitors;

sales of the our common stock or other securities in the open market; and

other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

***Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock.***

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of our common stock. There can be no assurance that the we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently quoted on the OTCQX.

***Our common stock is controlled by insiders.***

Our executive officers and directors beneficially own approximately 16% of our outstanding shares of common stock, and Dr. Gabor Forgacs, the father of one of our directors, beneficially owns another 9.7% of our outstanding shares of common stock. Although we are not aware of any voting arrangements between our officers, directors and Dr. Forgacs, such concentrated control may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations. Sales by our insiders or affiliates, along with any other market transactions, could affect the market price of our common stock.

***We do not intend to pay dividends for the foreseeable future.***

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment.

## **Table of Contents**

*Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.*

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and

require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

### **Item 1B. Unresolved Staff Comments.**

Not applicable.

### **Item 2. Properties.**

The Company entered into a new facilities lease at 6275 Nancy Ridge Drive, Suite 110, San Diego, CA 92121, signed on February 27, 2012 and with occupancy as of July 15, 2012. The base rent under the lease is approximately \$38,800 per month with 3% annual escalators. The lease term is 48 months with an option for the Company to extend the lease at the end of the lease term.

### **Item 3. Legal Proceedings.**

From time to time we may be named in claims arising in the ordinary course of business. Currently, we are not a party in any material legal proceedings.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****Market Information for Common Stock**

Organovo Holdings, Inc. is traded under the symbol ONVO, on the QX tier of the OTC; it was upgraded from the QB tier as of October 8, 2012.

The following table sets forth, on a per share basis, for the periods indicated, the high and low sales prices of our common stock.

<i>Year Ended December 31,</i>	High	Low
Fourth Quarter	3.39	1.80
Third Quarter	4.43	1.49
Second Quarter	10.90	2.00
First Quarter	2.65	1.24

As of March 1, 2013, there were 259 holders of record of the Company's common stock, and the closing price was \$4.10.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

**Merger Transaction**

On February 8, 2012, Organovo, Inc., a privately held Delaware corporation, merged with and into Organovo Acquisition Corp., a wholly-owned subsidiary of the Company, a publicly traded Delaware corporation, with Organovo, Inc. surviving the merger as a wholly-owned subsidiary of the Company (the "Merger"). As a result of the Merger, the Company acquired the business of Organovo, Inc., and will continue the existing business operations of Organovo, Inc.

Simultaneously with the Merger, on February 8, 2012 (the "closing date"), all of the issued and outstanding shares of Organovo, Inc.'s common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value \$0.001 per share. Also, on the closing date, all of the issued and outstanding options to purchase shares of Organovo, Inc.'s common stock and other outstanding warrants to purchase Organovo, Inc.'s common stock, and all of the issued and outstanding bridge warrants to purchase shares of Organovo, Inc.'s common stock, converted, respectively, on a 1 for 1 basis, into options, warrants and new bridge warrants to purchase shares of the Company's common stock.

Immediately following the consummation of the Merger: (i) the former security holders of Organovo, Inc. common stock had an approximate 75% voting interest in the Company and the Company stockholders retained an approximate 25% voting interest, (ii) former executive management team of Organovo, Inc. remained as the only continuing executive management team for the Company, and (iii) the Company's ongoing operations consist solely of the ongoing operations of Organovo, Inc. Based primarily on these factors, the Merger was accounted for as a reverse merger and a recapitalization in accordance with accounting principles generally accepted in the U.S. ("GAAP"). As a result, these consolidated financial statements reflect the historical results of Organovo, Inc. prior to the Merger, and the combined results of the Company following the Merger. The par value of Organovo, Inc. common stock immediately prior to the Merger was \$0.0001 per share. The par value subsequent to the Merger is \$0.001 per share, and therefore the historical results of Organovo, Inc. prior to the Merger have been retroactively adjusted to affect the change in par value.

**Table of Contents**

In connection with a private placement transaction completed in connection with the Merger (the Private Placement ), the Company received aggregate gross proceeds of approximately \$15.2 million. Proceeds of \$5.0 million, \$1.8 million and \$6.9 million were received on February 8, 2012, February 29, 2012 and March 16, 2012, respectively. In 2011 the Company received \$1,500,000 from the purchase of 6% convertible notes which were automatically converted into 1,500,000 shares of common stock, plus 25,387 shares for accrued interest of \$25,387 on the principal, at February 8, 2012.

The cash transaction costs related to the Merger were approximately \$2.1 million.

Before the Merger, Organovo Holdings Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the 2012 Plan ). The 2012 Plan provides for the issuance of 6,553,986 shares of the Company s common stock to executive officers, directors, advisory board members and employees. In addition, Organovo Holdings assumed and adopted Organovo, Inc. s 2008 Equity Incentive Plan. The Company does not intend to issue any additional shares from the 2008 Equity Incentive Plan.

**Item 6. Selected Financial Data**

This item has been omitted as the Company qualifies as a smaller reporting company.

**Table of Contents****Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*The following management's discussion and analysis should be read in conjunction with Organovo's historical consolidated financial statements and the related notes. This management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Annual Report. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this Annual Report. Except as required by applicable law we do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.*

*The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires Organovo to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, Organovo evaluates such estimates and judgments, including those described in greater detail below. Organovo bases its estimates on historical experience and on various other factors that Organovo believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.*

**Overview**

We have developed and are commercializing a platform technology for the generation of functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by creation of constructs in 3D that have the potential to replicate native human biology. We can improve on previous technologies by moving away from monolayer 2D cell cultures and by enabling all or part of tissues we create to be constructed solely of cells. We believe our expertise in printing various fully cellular human tissues, as disclosed in peer-reviewed scientific publications, provides a strong foundation upon which other tissues can be built to replicate human biology and human disease. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, combined with strengths in engineering and biology, put us in an ideal position to provide a wide array of products for use in research, drug discovery and regenerative medicine therapies.

*Reverse Merger Transaction*

On February 8, 2012, Organovo Acquisition Corp. ( "Acquisition Corp." ), a wholly-owned subsidiary of Organovo Holdings, Inc., merged (the "Merger") with and into Organovo, Inc., a privately held Delaware corporation ( "Organovo" ). Organovo was the surviving corporation of that Merger. As a result of the Merger, the Company acquired the business of Organovo, and will continue the existing business operations of Organovo as a wholly-owned subsidiary.

Simultaneously with the Merger, on the Closing Date, all of the issued and outstanding shares of Organovo common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value \$0.001 per share ( "Common Stock" ). Also on the Closing Date, all of the issued and outstanding options to purchase shares of Organovo Common Stock, all of the issued and outstanding Bridge Warrants (as defined below) to purchase shares of Organovo Common Stock, and other outstanding warrants to purchase Organovo Common Stock converted, respectively, into options (the "New Options"), new bridge warrants (the "New Bridge



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## **Table of Contents**

Warrants ) and new warrants (the New Warrants ) to purchase shares of Common Stock. The New Bridge Warrants, the New Warrants and New Bridge Options were converted on a 1 for 1 basis. The New Options will be administered under Organovo's 2008 Equity Incentive Plan (the 2008 Plan ), which the Company assumed and adopted on the Closing Date in connection with the Merger.

Specifically, on the Closing Date, (i) 22,445,254 shares of Common Stock were issued to former Organovo stockholders; (ii) New Options to purchase 896,256 shares of Common Stock granted under the 2008 Plan were issued to optionees pursuant to the assumption of the 2008 Plan; (iii) New Warrants to purchase 1,309,750 shares of Common Stock at \$1.00 per share were issued to holders of Organovo warrants; and (iv) New Bridge Warrants to purchase 1,500,000 shares of Common Stock at \$1.00 per share were issued to Bridge Investors (as defined below).

Additionally, New Warrants to purchase 100,000 shares of Common Stock at \$1.00 per share were issued to a former noteholder of Organovo in connection with the repayment at the Closing Date of a promissory note in the principal amount of \$100,000.

The Merger was treated as a recapitalization of the Company for financial accounting purposes. The historical financial statements of Organovo Holdings, Inc. before the Merger were replaced with the historical financial statements of Organovo before the Merger.

Before the Merger, Organovo Holdings, Inc.'s Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the 2012 Plan ). The 2012 Plan provides for the issuance of up to 6,553,986 shares, or approximately 11% of our December 31, 2012 outstanding Common Stock, to executive officers, directors, advisory board members and employees. In addition, we assumed and adopted the 2008 Plan, and as described above option holders under that plan were granted New Options to purchase Common Stock. No further options will be granted under the 2008 Plan. The parties have taken all actions necessary to ensure that the Merger was treated as a tax free exchange under Section 368(a) of the Internal Revenue Code of 1986, as amended.

As of March 1, 2013, the Company had 62,237,772 total issued and outstanding shares of Common Stock, and five year warrants for the opportunity to purchase an additional 7,359,149 shares of Common Stock at exercise prices ranging from \$1.00 to \$3.24 per share. If all warrants were exercised on a cash basis, the Company would realize approximately \$8.1 million in additional gross proceeds.

### ***Critical Accounting Policies***

Our consolidated financial statements, which appear under Item 8 of Part II have been prepared in accordance with accounting principles generally accepted in the United States, which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 1 to our consolidated financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

### **Revenue Recognition**

The Company's revenues are derived from collaborative research agreements, National Institute of Health ( NIH ) and U.S. Treasury Department Grants, the sale of bioprinter related products and services, and license agreements.

The Company recognizes revenue when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) services have been rendered or product has been delivered; (iii) price to the customer is fixed and determinable; and (iv) collection of the underlying receivable is reasonably assured.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met.

## **Table of Contents**

### *Product Revenue*

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. The Company recognizes product revenues upon shipment to distributors, provided that (i) the price is substantially fixed or determinable at the time of sale; (ii) the distributor's obligation to pay the Company is not contingent upon resale of the products; (iii) title and risk of loss passes to the distributor at time of shipment; (iv) the distributor has economic substance apart from that provided by the Company; (v) the Company has no significant obligation to the distributor to bring about resale of the products; and (vi) future returns can be reasonably estimated. For any sales that do not meet all of the above criteria, revenue is deferred until all such criteria have been met. The Company's collaboration revenue consists of license and collaboration agreements that contain multiple elements, including non-refundable upfront fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. The Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

### *Collaborative and License Revenue*

The Company recognizes revenue from research funding under collaboration agreements when earned on a proportional performance basis as research hours are incurred. The Company performs services as specified in each respective agreement on a best-efforts basis, and is reimbursed based on labor hours incurred on each contract. The Company initially defers revenue for any amounts billed, or payments received, in advance of the services being performed and recognizes revenue pursuant to the related pattern of performance, based on total labor hours incurred relative to total labor hours estimated under the contract.

### *Revenue Arrangements with Multiple Deliverables*

The Company occasionally enters into revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using Vendor Specific Objective Evidence (VSOE) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect the Company's results of operations.

### *NIH Grant Revenues*

Revenues from the NIH grants are based upon internal and subcontractor costs incurred that are specifically covered by the grants, and where applicable, an additional facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors and as the Company incurs internal expenses that are related to the grants.

## **Table of Contents**

### *Allowance for Doubtful Accounts*

When we begin to sell commercial product we expect to establish a reserve for estimated sales returns that will be recorded as a reduction to revenue. That reserve will be maintained to account for future return of products sold in the current period. The reserve will be reviewed quarterly and will be estimated based on an analysis of our historical experience related to product returns.

### *Derivative Financial Instruments*

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks.

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, the Company may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

### *Fair Value Measurements*

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company uses Level 3 inputs for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions. The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to fair value of derivative liabilities.

## **Table of Contents**

### **Stock-Based Compensation**

For purposes of calculating stock-based compensation, we estimate the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

### **Results of Operations**

#### **Overview**

Organovo was founded in Delaware in April 2007. Activities since the Company's inception through 2012 were devoted primarily to developing a platform technology for the generation of functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs.

As of December 31, 2012, the Company had devoted substantially all of its efforts to product development, raising capital and building infrastructure. The Company has not realized significant revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

#### ***Comparison of the years ended December 31, 2012 and 2011***

#### **Revenues**

2012 total revenues of \$1.2 million increased \$0.2 million, or 20%, over 2011 revenues of \$1.0 million. That increase was due to a \$0.3 million increase in collaborative agreement revenues, and a \$0.1 million increase in grant revenues, partially offset by a \$0.2 million reduction in product revenues. While grant revenues are not expected to increase significantly in 2013, they will represent a portion of total revenues while the Company focuses efforts on collaborative agreements and continued development of research tools.

#### **Operating Expenses**

Operating expenses increased approximately \$7.2 million, or 218%, in 2012 over 2011, from \$3.3 million in 2011 to \$10.5 million in 2012. Most significantly, relative to the prior year, the Company invested in infrastructure and outside services to support its transition from private ownership to a publicly owned and traded corporation. As expected in such transition, incremental initiatives were established in investor outreach, corporate governance, and SEC financial reporting. Non-payroll related incremental public company expenses incurred in 2012 were approximately \$3.2 million. Moreover, the Company invested in building its executive, research, and development staff, increasing payroll related expenses by \$2.0 million or 154% over 2011, from \$1.3 million to \$3.3 million. The increase in payroll-related expenses accounted for approximately 28% of total year-to-year increase in operating expenses. Stock-based compensation expense increased by approximately \$1.4 million compared to the prior year under the 2012 Equity Incentive Plan with awards granted related to increased headcount in line with expanded operations. Additionally, the Company consolidated and relocated its facilities to a larger space to accommodate its growing research operations staff at an incremental cost over 2011 of approximately \$0.3 million.

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## **Table of Contents**

### **Research and Development Expenses**

2012 research and development expenses of \$3.4 million increased by approximately \$2.0 million, or 143%, over 2011 expenses of \$1.4 million as the Company increased its research staff to support its obligations under certain collaborative research agreements and to expand product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from eight scientists and engineers as of December 31, 2011 to nineteen as of December 31, 2012.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses grew from \$1.7 million in 2011 to \$7.1 million in 2012, an increase of \$5.4 million or 318%. Expense increases were driven by non-recurring charges associated with the financing, increased payroll and facilities expenses and our transition from operating in a private company environment to operating in a publicly traded corporation. As expected in such transition, incremental initiatives were established in investor outreach, corporate governance, and SEC financial reporting. Non-payroll related incremental public company expenses incurred in 2012 were approximately \$3.2 million including non-recurring charges associated with the Merger and the Private Placements completed during the year. In addition, expanded staff increased payroll and facilities expenses in 2012 over 2011 levels with general and administrative staff increasing from four full-time employees as of December 31, 2011 to ten full-time employees as of December 31, 2012. This increase was primarily due to the addition of two executive positions and a small number of accounting and administrative staff. In addition, existing executive officers received salary increases as approved by the Board of Directors, reflecting the increased responsibilities assumed as a result of becoming a publicly traded company and success on growth initiatives.

### **Other Income (Expense)**

The \$32.2 million increase in other expenses as compared to 2011 was primarily related to the non-cash transaction costs associated with the Merger, the 2012 Private Placement, and the Tender Offer loss on the inducement to exercise warrants. We issued warrants to purchase 6,099,195 shares of our common stock to the placement agent and warrants to purchase 15,247,987 of our common stock to investors in the Private Placement. The warrants issued to the placement agent and Private Placement investors were determined to be derivative liabilities as a result of the anti-dilution provisions in the warrant agreements that may result in an adjustment to the warrant exercise price. We revalue the derivative liability on each subsequent balance sheet date until the securities to which the derivatives liabilities relate are exercised or expire. The fair value of warrant liabilities in excess of proceeds received was \$19.0 million, while the change in fair value of warrant liabilities was \$9.9 million. Financing transaction costs in excess of proceeds received was \$2.1 million, the loss on inducement to exercise warrants under the Tender Offer was \$1.9 million, and our interest expense was \$1.1 million. 2012 interest expense was primarily comprised of non-cash components including accretion of debt discounts and amortization of deferred financing costs. The \$2.1 million of interest expense in 2011 was primarily comprised of non-cash components including \$1.2 million in amortization of debt discounts, \$0.6 million fair value of warrants issued in connection with the 2011 Exchange Agreement (see Note 5) and amortization of deferred financing costs of \$0.1 million.

Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Future changes in these factors will have a significant impact on the computed fair value of the warrant liability. As such, we expect future changes in the fair value of the warrants to continue to vary significantly from quarter to quarter.

### **Financial Condition, Liquidity and Capital Resources**

Since its inception, the Company has primarily devoted its efforts to research and development, business planning, raising capital, recruiting management and technical staff, and acquiring operating assets. Accordingly, the Company is considered to be in the development stage.

## **Table of Contents**

Since inception, the Company incurred negative cash flows from operations. As of December 31, 2012, the Company had cash and cash equivalents of \$14.8 million and an accumulated deficit of \$50.2 million. The Company also had negative cash flow from operations of \$9.7 million during the year ended December 31, 2012. The increase in the net cash used in operating activities for the year ended December 31, 2012 was primarily due to our increased net loss.

At December 31, 2012, we had total current assets of \$15.9 million and current liabilities of \$22.0 million, resulting in a working capital deficit of \$6.1 million. At December 31, 2011, we had total current assets of \$1.0 million and current liabilities of \$2.0 million, resulting in a working capital deficit of \$1.0 million.

Net cash used in investing activities was \$0.4 million and \$0.1 million for the years December 31, 2012 and 2011, respectively. The increased use of net cash in investing activities was primarily due to purchases of equipment for the research lab.

Net cash provided by financing activities was \$24.6 million and \$2.1 million, for the years ended December 31, 2012 and 2011, respectively. The increase in cash provided by financing activities in 2012 was primarily due to proceeds received from the issuance of common stock and the exercise of warrants during the year. During February and March 2012, the Company received gross proceeds of \$13.7 million from the private placement of equity securities. On February 8, February 29, and March 16, 2012, the Company completed the first, second and final closings, respectively, of the private placement offering. In these three closings, the Company issued 6,525,887 Units, 1,806,100 Units, and 6,916,000 Units, respectively, to accredited investors at a price of \$1.00 per Unit, including the conversion of \$1.5 million of principal and \$25,379 of accrued interest under certain bridge promissory notes issued in 2011. The first closing was conducted simultaneously with the completion of the Company's merger (the Merger) with Organovo, Inc. Each Unit consisted of one share of common stock of the Company, \$0.001 par value per share and a five-year warrant to purchase one share of common stock at \$1.00 per share. Total net proceeds were \$11.6 million (or \$12.8 million, including the conversion of the bridge promissory notes referred to above). In addition, the Company consummated its Warrant Tender Offer in December 2012 to amend certain of its outstanding warrants to purchase approximately 14.5 million shares of the Company's common stock. The Warrant Tender Offer, which expired on December 21, 2012, resulted in approximately 9.6 million warrants tendered by their holders for aggregate proceeds of approximately \$7.7 million.

The Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, and through revenue derived from grants or collaborative research agreements. Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next 12 months.

The Company will need additional capital to further fund product development and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through additional financing from existing and prospective investors, and from revenue derived from grants and collaborative research agreements. However, we may not be successful in obtaining funding from new or existing collaborative research agreements. In addition, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. Further, the NIH has notified all grant recipients that due to the current Congressional budget sequestration, the NIH may not be able to issue continuation awards, or it may be required to negotiate a reduction in the scope of existing awards to meet the constraints imposed. Additionally, plans for new grants or cooperative agreements may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources. As a result, we cannot assure you that we will receive the funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

**Table of Contents**

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

This information has been omitted as the Company qualifies as a smaller reporting company.

**Table of Contents**

**Item 8. Consolidated Financial Statements and Supplementary Data**

**Organovo Holdings, Inc.**

(A development stage company)

**Index to Consolidated Financial Statements**

	<b>Page Number</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	F-3
<u>Consolidated Statements of Operations as of December 31, 2012 and 2011, and from April 19, 2007 (Inception) through December 31, 2012</u>	F-4
<u>Consolidated Statements of Stockholders' Deficit from April 19, 2007 (Inception) through December 31, 2012</u>	F-5
<u>Consolidated Statements of Cash Flows as of December 31, 2012 and 2011, and from April 19, 2007 (Inception) through December 31, 2012</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-8

F-1



**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

**Organovo Holdings, Inc.**

San Diego, California

We have audited the accompanying consolidated balance sheets of **Organovo Holdings, Inc and Subsidiary** (the Company ) as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended and for the period from April 19, 2007 (Inception) through December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of **Organovo Holdings, Inc and Subsidiary** as of December 31, 2012 and 2011, and the results of their consolidated operations and its cash flows for the years then ended and for the period from April 19, 2007 (Inception) through December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

March 15, 2013

**Table of Contents****ORGANOVO HOLDINGS, INC.**

(A development stage company)

**CONSOLIDATED BALANCE SHEETS**

(in thousands except per share data)

	December 31, 2012	December 31, 2011
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 14,817	\$ 340
Grant receivable	162	
Inventory	360	292
Deferred financing costs		319
Prepaid expenses and other current assets	527	80
Total current assets	15,866	1,031
<b>Fixed Assets - Net</b>	<b>714</b>	<b>278</b>
<b>Restricted Cash</b>	<b>88</b>	
<b>Other Assets - Net</b>	<b>81</b>	<b>100</b>
Total assets	\$ 16,749	\$ 1,409
<b>Liabilities and Stockholders Deficit</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 425	\$ 658
Accrued expenses	981	438
Deferred revenue		153
Capital lease obligation, current portion	10	
Accrued interest payable		24
Convertible notes payable, current portion		704
Warrant liabilities, current	20,619	
Total current liabilities	22,035	1,977
Warrant liabilities, non-current		1,267
Capital lease obligation, net of current portion	17	
Total liabilities	\$ 22,052	\$ 3,244
<b>Commitments and Contingencies (see Note 7)</b>		
<b>Stockholders Deficit</b>		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 58,535,411 and 22,445,254 shares issued and outstanding at December 31, 2012 and December 31, 2011, respectively	59	22
Additional paid-in capital	44,883	4,835
Deficit accumulated during the development stage	(50,245)	(6,692)
Total stockholders deficit	(5,303)	(1,835)
<b>Total Liabilities and Stockholders Deficit</b>	<b>\$ 16,749</b>	<b>\$ 1,409</b>

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*The accompanying notes are an integral part of these consolidated financial statements.*

F-3

**Table of Contents****ORGANOVO HOLDINGS, INC.**

(A development stage company)

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands except per share data)

	Year Ended December 31, 2012	Year Ended December 31, 2011	<i>Period from April 19, 2007 (Inception) through December 31, 2012</i>
<b>Revenue</b>			
Product	\$	\$ 224	\$ 224
Collaborations	1,035	688	1,798
Grants	162	57	826
<b>Total Revenue</b>	<b>1,197</b>	<b>969</b>	<b>2,848</b>
Cost of product revenue		121	134
Selling, general, and administrative expenses	7,080	1,733	9,747
Research and development expenses	3,436	1,420	6,634
<b>Loss from Operations</b>	<b>(9,319)</b>	<b>(2,305)</b>	<b>(13,667)</b>
<b>Other Income (Expense)</b>			
Fair value of warrant liabilities in excess of proceeds received	(19,019)		(19,019)
Change in fair value of warrant liabilities	(9,931)	(7)	(9,938)
Financing transaction costs in excess of proceeds received	(2,130)		(2,130)
Loss on inducement to exercise warrants	(1,904)		(1,904)
Loss on disposal of fixed assets	(158)		(158)
Interest expense	(1,088)	(2,067)	(3,406)
Interest income	5		7
Other expense	(9)	(4)	(30)
<b>Total Other Income (Expense)</b>	<b>(34,234)</b>	<b>(2,078)</b>	<b>(36,578)</b>
<b>Net Loss</b>	<b>\$ (43,553)</b>	<b>\$ (4,383)</b>	<b>\$ (50,245)</b>
<b>Net loss per common share - basic and diluted</b>	<b>\$ (1.01)</b>	<b>\$ (0.19)</b>	
<b>Weighted average number of shares used in computing net loss per share - basic and diluted</b>	<b>43,149,657</b>	<b>22,925,694</b>	

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****ORGANOVO HOLDINGS, INC.**

(A development stage company)

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT**(in thousands) *Period from April 19, 2007 (Inception) through December 31, 2012*

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity
	Number of Shares	Amount			
<b>Balance at inception (April 19, 2007)</b>		\$	\$	\$	\$
Issuance of common stock					
Stock-based compensation expense					
Net Loss					
<b>Balance at December 31, 2007</b>		\$	\$	\$	\$
Issuance of common stock to founders	1,730	2	(2)		
Issuance of restricted common stock	12,628	12	(12)		
Stock-based compensation expense			2		2
Net Loss				(98)	(98)
<b>Balance at December 31, 2008</b>	<b>14,358</b>	<b>\$ 14</b>	<b>\$ (12)</b>	<b>\$ (98)</b>	<b>\$ (96)</b>
Issuance of restricted common stock	130				
Stock-based compensation expense			2		2
Net Loss				(872)	(872)
<b>Balance at December 31, 2009</b>	<b>14,488</b>	<b>\$ 14</b>	<b>\$ (10)</b>	<b>\$ (970)</b>	<b>\$ (966)</b>
Issuance of restricted common stock	219				
Stock-based compensation expense			4		4
Net Loss				(1,339)	(1,339)
<b>Balance at December 31, 2010</b>	<b>14,707</b>	<b>\$ 14</b>	<b>\$ (6)</b>	<b>\$ (2,309)</b>	<b>\$ (2,301)</b>
Issuance of common stock through conversion of notes payable	7,677	8	3,482		3,490
Issuance of restricted common stock	61				
Warrants issued with convertible notes and upon conversion of notes payable			1,111		1,111
Beneficial conversion feature of convertible notes payable			239		239
Stock-based compensation expense			9		9
Net Loss				(4,383)	(4,383)
<b>Balance at December 31, 2011</b>	<b>22,445</b>	<b>\$ 22</b>	<b>\$ 4,835</b>	<b>\$ (6,692)</b>	<b>\$ (1,835)</b>
Issuance of common stock in connection with merger	6,000	6	(6)		
Issuance of common stock through private placements in connection with reverse merger	13,723	14	13,709		13,723
Costs associated with merger			(13,723)		(13,723)
Issuance of common stock through conversion of notes payable and accrued interest in connection with merger	1,525	2	1,524		1,526
Issuance of warrants to consultants			890		890
Issuance of common stock from warrant exercises, net	13,424	14	10,977		10,991

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Issuance of restricted common stock	1,380	1	(1)		
Restricted stock forfeitures	(186)				
Warrant liability removed due to exercises of warrants			23,321	23,321	
Issuances of common stock from stock option exercise	224		18	18	
Stock-based compensation expense			1,435	1,435	
Loss on inducement to exercise warrants			1,904	1,904	
Net Loss				(43,553)	(43,553)
<b>Balance at December 31, 2012</b>	<b>58,535</b>	<b>\$ 59</b>	<b>\$ 44,883</b>	<b>\$ (50,245)</b>	<b>\$ (5,303)</b>

*The accompanying notes are an integral part of these consolidated financial statements.*

F-5

**Table of Contents****ORGANOVO HOLDINGS, INC.**

(A development stage company)

**CONSOLIDATED STATEMENTS OF CASH FLOWS** (in thousands)

	Year Ended December 31, 2012	Year Ended December 31, 2011	<i>Period from April 19, 2007 (Inception) through December 31, 2012</i>
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (43,553)	\$ (4,383)	\$ (50,245)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt discount	896	1,188	2,084
Loss on disposal of fixed assets	158		158
Depreciation and amortization	195	68	351
Amortization of deferred financing costs	319	119	438
Amortization of warrants issued for services	556		556
Interest accrued on convertible notes payable	12	232	495
Warrants issued in connection with exchange agreement		528	528
Loss on inducement to exercise warrants	1,904		1,904
Stock-based compensation	1,435	9	1,452
Fair value of warrant liabilities in excess of proceeds	19,019		19,019
Change in fair value of warrant liabilities	9,931	7	9,938
Increase (decrease) in cash resulting from changes in:			
Grants receivable	(162)	60	(162)
Inventory	(459)	(224)	(751)
Prepaid expenses and other current assets	(101)	(69)	(194)
Accounts payable	(233)	373	425
Accrued expenses	543	132	981
Deferred revenue	(153)	46	
<b>Net cash used in operating activities</b>	<b>(9,693)</b>	<b>(1,914)</b>	<b>(13,023)</b>
<b>Cash Flows From Investing Activities</b>			
Restricted cash deposits	(88)		(88)
Purchases of fixed assets	(357)	(46)	(784)
Purchases of intangible assets		(65)	(95)
<b>Net cash used in investing activities</b>	<b>(445)</b>	<b>(111)</b>	<b>(967)</b>
<b>Cash Flows From Financing Activities</b>			
Proceeds from issuance of convertible notes payable		2,543	4,630
Proceeds from issuance of common stock and exercise of warrants, net	24,714		24,714
Proceeds from exercise of stock options	18		18
Proceeds from issuance of related party notes payable		225	250
Repayment of related party notes payable		(250)	(250)
Repayment of convertible notes and interest payable	(110)		(110)
Principal payments on capital lease obligations	(7)		(7)
Deferred financing costs		(438)	(438)
<b>Net cash provided by financing activities</b>	<b>24,615</b>	<b>2,080</b>	<b>28,807</b>

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<b>Net Increase in Cash and Cash Equivalents</b>	14,477	55	14,817
<b>Cash and Cash Equivalents at Beginning of Period</b>	340	285	
<b>Cash and Cash Equivalents at End of Period</b>	\$ 14,817	\$ 340	\$ 14,817
<b>Supplemental Disclosures of Cash Flow Information:</b>			
Interest	\$ 10	\$	\$ 10
Income Taxes	\$ 1	\$ 1	\$ 3

*The accompanying notes are an integral part of these consolidated financial statements.*

F-6



**Table of Contents**

**Supplemental Disclosure of Noncash Investing and Financing Activities:**

During 2011, the Company issued certain convertible notes payable that included warrants. The related beneficial conversion feature, valued at \$823,000 was classified as an equity instrument and recorded as a discount to the carrying value of the related debt. The warrants, valued at approximately \$1,260,000, were recorded as a warrant liability and recorded as a discount to the carrying value related to debt.

During 2011, the Company issued 7,676,828 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$3,030,000 and accrued interest totaling \$460,000.

During 2012, the Company issued 1,525,387 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$1,500,000 and accrued interest totaling \$25,000.

During 2012, the Company issued warrants, valued at approximately \$32,743,000, in connection with the Reverse Merger and the Private Placement. The warrants were recognized as a derivative liability.

During 2012, the Company purchased equipment valued at \$34,000 through a capital lease.

During 2012, the Company transferred approximately \$391,000 of bioprinter related inventory to fixed assets.

During 2012, the Company issued 650,000 warrants to purchase shares of our common stock for consulting services. The warrants were valued at approximately \$890,000.

During 2012, the warrant liability was reduced by \$23,321,000 as a result of settlements during the year.

*The accompanying notes are an integral part of these consolidated financial statements.*

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**Table of Contents**

**Organovo Holdings, Inc.**

**(A development stage company)**

**Notes to Consolidated Financial Statements**

**1. Summary of Significant Accounting Policies** A summary of significant accounting policies, consistently applied in the preparation of the accompanying consolidated financial statements follows:

*Nature of operations and basis of presentation*

Organovo Holdings, Inc., ( the Company ), through its wholly-owned subsidiary, Organovo, Inc., a Delaware corporation, has devoted substantially all of its resources to product development, raising capital, and building infrastructure. The Company has developed and is commercializing a platform technology for the generation of functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs.

All of the Company's potential products are in research and development phases and as of December 31, 2012, the Company has not generated revenue from its planned principal operations. The Company does earn revenue from research and development agreements with collaborators and grants from governmental entities. Accordingly, the Company is considered to be in the development stage.

*Reverse merger transaction*

On February 8, 2012, Organovo, Inc., a privately held Delaware corporation, merged with and into Organovo Acquisition Corp., a wholly-owned subsidiary of Organovo Holdings, Inc., a publicly traded Delaware corporation, with Organovo, Inc. surviving the merger as a wholly-owned subsidiary of the Company (the Merger ). As a result of the Merger, the Company acquired the business of Organovo, Inc., and will continue the existing business operations of Organovo, Inc.

Simultaneously with the Merger, on February 8, 2012 (the closing date ), all of the issued and outstanding shares of Organovo, Inc.'s common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value \$0.001 per share. Also, on the closing date, all of the issued and outstanding options to purchase shares of Organovo, Inc.'s common stock and other outstanding warrants to purchase Organovo, Inc.'s common stock, and all of the issued and outstanding bridge warrants to purchase shares of Organovo, Inc.'s common stock, converted, respectively, on a 1 for 1 basis, into options, warrants and new bridge warrants to purchase shares of the Company's common stock.

Immediately following the consummation of the Merger: (i) the former security holders of Organovo, Inc. common stock had an approximate 75% voting interest in the Company and the Company stockholders retained an approximate 25% voting interest, (ii) former executive management team of Organovo, Inc. remained as the only continuing executive management team for the Company, and (iii) the Company's ongoing operations consist solely of the ongoing operations of Organovo, Inc. Based primarily on these factors, the Merger was accounted for as a reverse merger and a recapitalization in accordance with accounting principles generally accepted in the United States ( GAAP ). As a result, these financial statements reflect the historical results of Organovo, Inc. prior to the Merger, and the combined results of the Company following the Merger. The par value of Organovo, Inc. common stock immediately prior to the Merger was \$0.0001 per share. The par value subsequent to the Merger is \$0.001 per share, and therefore the historical results of Organovo, Inc. prior to the Merger have been retroactively adjusted to affect the change in par value.

In connection with three separate closings of a private placement transaction completed in connection with the Merger (the Private Placement ), the Company received gross proceeds of approximately \$5.0 million, \$1.8 million and \$6.9 million on closings on February 8, 2012, February 29, 2012 and March 16, 2012, respectively. In 2011, the Company received \$1.5 million from the purchase of 6% convertible notes which were

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**Table of Contents**

automatically converted into 1,500,000 shares of common stock, plus 25,387 shares for accrued interest of \$25,387 on the principal, on February 8, 2012.

The cash transaction costs related to the Merger were approximately \$2.1 million.

Before the Merger, Organovo Holdings' Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of 6,553,986 shares of the Company's common stock to executive officers, directors, advisory board members and employees. In addition, Organovo Holdings assumed and adopted Organovo, Inc.'s 2008 Equity Incentive Plan, which provided for the issuance of 896,256 shares of common stock, for total shares available for issuance under these plans of 7,450,242.

*Liquidity*

As of December 31, 2012, the Company had an accumulated deficit of approximately \$50.2 million. The Company also had negative cash flows from operations of approximately \$9.7 million during the year ended December 31, 2012.

On February 8, 2012, the Company received gross proceeds of approximately \$5.0 million from the initial closing of a private placement offering in conjunction with the Merger (the "Private Placement"). On February 29, 2012 and March 16, 2012, the Company completed two additional closings of its Private Placement receiving gross proceeds of approximately \$1.8 million and \$6.9 million respectively.

On December 21, 2012, the Company consummated its Warrant Tender Offer to amend certain of its outstanding warrants to purchase approximately 14.5 million shares of the Company's common stock. The Warrant Tender Offer, which expired on December 21, 2012, resulted in approximately 9.6 million warrants tendered by their holders for aggregate proceeds of approximately \$7.7 million.

Subsequent to December 31, 2012, on February 5, 2013, the Company provided a Notice of Redemption to affected warrant holders, of approximately 2.4 million warrant shares, that they would have until March 14, 2013 to exercise their outstanding warrants at \$1.00 per share. Thereafter, any warrants that remain unexercised will automatically be redeemed by the Company at a redemption price of \$0.0001 per share of common stock then issuable upon exercise of the redeemed warrant. As of March 14, 2013, all redeemable warrants had been exercised for proceeds of approximately \$2.3 million.

The Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, and through revenue derived from grants or collaborative research agreements. Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next 12 months.

The Company will need additional capital to further fund product development and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through additional financing from existing and prospective investors, and from revenue derived from grants and collaborative research agreements. However, we may not be successful in obtaining funding from new or existing collaborative research agreements. In addition, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. Further, the NIH has notified all grant recipients that due to the current Congressional budget sequestration, the NIH may not be able to issue continuation awards, or it may be required to negotiate a reduction in the scope of existing awards to meet the constraints imposed. Additionally, plans for new grants or cooperative agreements may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources. As a result, we cannot assure you that we will receive the funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

## **Table of Contents**

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

### *Use of estimates*

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates used in preparing the consolidated financial statements include those assumed in computing the valuation of warrants and conversion features, revenue recognized under the proportional performance model, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets.

### *Financial instruments*

For certain of the Company's financial instruments, including cash and cash equivalents, grants receivable, inventory, prepaid expenses and other assets, accounts payable, accrued expenses, deferred revenue and convertible notes payable, the carrying amounts are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

### *Cash and cash equivalents*

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents.

### *Derivative financial instruments*

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency.

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where a host instrument contains more than one embedded derivative instrument, including a conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, the Company may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

The discount from the face value of the convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to interest expense, using the effective interest method.

## **Table of Contents**

### *Restricted cash*

As of December 31, 2012, the Company had approximately \$88,300 of restricted cash deposited with a financial institution. \$38,300 is held in certificates of deposit to support a letter of credit agreement related to the facility lease entered into during 2012. The additional \$50,000 is held by the financial institution as a guarantee for the Company's commercial credit cards.

### *Grant receivable*

Grant receivable represents the amount due from the NIH under a research grant. The Company considers the grant receivable to be fully collectible; and accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

### *Inventory*

Inventories are stated at the lower of the cost or market (first-in, first-out). Inventory at December 31, 2012 consisted of approximately \$196,000 in finished goods, \$60,000 work-in-process and \$104,000 in raw materials. Inventory at December 31, 2011 consisted of approximately \$204,000 in finished goods, \$24,000 in work-in-process and \$64,000 in raw materials.

The Company provides inventory allowances based on excess or obsolete inventories determined based on anticipated use in the final product. There was no obsolete inventory reserve as of December 31, 2012 or December 31, 2011.

### *Deferred financing costs*

As of December 31, 2012, there were no deferred financing costs. As of December 31, 2011, deferred financing costs consisted of approximately \$140,000 associated with the Merger transaction and approximately \$179,000 associated with convertible notes as part of the private placement offering that was initiated in the fourth quarter of 2011. The deferred financing costs related to the private placement offering were being amortized over the life of the convertible notes and were fully amortized to expense upon conversion of the convertible notes on February 8, 2012. The deferred financing costs associated with the Merger transaction were recorded as an offset to the proceeds received, with the amount in excess of the proceeds received expensed at the effective Merger date.

### *Fixed assets and depreciation*

Property and equipment are carried at cost. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the lease term. The estimated useful lives of the fixed assets ranges between two and five years.

### *Impairment of long-lived assets*

In accordance with authoritative guidance the Company reviews its long-lived assets, including property and equipment and other assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, the Company evaluates whether future undiscounted net cash flows will be less than the carrying amount of the assets and adjusts the carrying amount of its assets to fair value. Management has determined that no impairment of long-lived assets occurred in the period from inception through December 31, 2012.

### *Fair value measurement*

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for

**Table of Contents**

the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2012 and December 31, 2011, cash and cash equivalents were comprised of cash in checking accounts.

The Company uses Level 3 inputs for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions (see Note 4). The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of derivative liabilities.

The estimated fair values of the liabilities measured on a recurring basis are as follows:

	<b>Fair Value Measurements at December 31, 2012 and 2011:</b>			
	<b>Balance at December 31, 2012</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Other Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 20,618,706			\$ 20,618,706

	<b>Fair Value Measurements at December 31, 2011:</b>			
	<b>Balance at December 31, 2011</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Other Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 1,266,869			\$ 1,266,869

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for 2011 and 2012:

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)**

	<b>Warrant Derivative Liability (\$000 s)</b>
Balance at December 31, 2010	\$
Issuances	1,260
Adjustments to estimated fair value	7
Balance at December 31, 2011	1,267
Issuances	32,742
Adjustments to estimated fair value	9,931
Warrant liability removal due to settlements	(23,321)

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Balance at December 31, 2012	\$	20,619
<i>Research and development</i>		

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs, as well as costs associated with sponsored research and development. Research and development costs are expensed as incurred.

F-12

## **Table of Contents**

### *Income taxes*

Deferred income taxes are recognized for the tax consequences in future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities.

### *Revenue recognition*

The Company's revenues are derived from collaborative research agreements, NIH and U.S. Treasury Department Grants, the sale of bioprinter related products and services, and license agreements.

The Company recognizes revenue when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) services have been rendered or product has been delivered; (iii) price to the customer is fixed and determinable; and (iv) collection of the underlying receivable is reasonably assured.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of December 31, 2012 and December 31, 2011, the Company had \$0 and \$152,500, respectively, in deferred revenue related to its collaborative research programs.

### *Product Revenue*

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. The Company recognizes product revenues upon shipment to distributors, provided that (i) the price is substantially fixed or determinable at the time of sale; (ii) the distributor's obligation to pay the Company is not contingent upon resale of the products; (iii) title and risk of loss passes to the distributor at time of shipment; (iv) the distributor has economic substance apart from that provided by the Company; (v) the Company has no significant obligation to the distributor to bring about resale of the products; and (vi) future returns can be reasonably estimated. For any sales that do not meet all of the above criteria, revenue is deferred until all such criteria have been met.

### *Research and Development Revenue Under Collaborative Agreements.*

The Company's collaboration revenue consists of license and collaboration agreements that contain multiple elements, including non-refundable upfront fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. The Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The Company recognizes revenue from research funding under collaboration agreements when earned on a proportional performance basis as research hours are incurred. The Company performs services as specified in each respective agreement on a best-efforts basis, and is reimbursed based on labor hours incurred on each contract. The Company initially defers revenue for any amounts billed or payments received in advance of the services being performed and recognizes revenue pursuant to the related pattern of performance, based on total labor hours incurred relative to total labor hours estimated under the contract.

In December 2010, the Company entered into a 12 month research contract agreement with a third party, whereby the Company was engaged to perform research and development services on a fixed-fee basis for



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## **Table of Contents**

approximately \$600,000. Based on the proportional performance criteria, the Company recognized approximately \$150,000 and \$450,000 in revenue related to the contract during the years ended December 31, 2012 and 2011, respectively. Total revenue recognized on the contract from inception through December 31, 2012 was approximately \$600,000.

In October 2011, the Company entered into a research contract agreement with a third party, whereby the Company will perform research and development services on a fixed-fee basis for \$1,365,000. The agreement included an initial payment to the Company of approximately \$239,000 with remaining payments expected to occur over a twenty-one month period. On November 27, 2012, the agreement was amended to include additional research and development services, for an additional \$135,000, bringing the total contract value to \$1,500,000. This extends the original contract (which runs concurrently) from twenty-one months to twenty-eight months. The Company recorded approximately \$885,000 and \$239,000 in 2012 and 2011, respectively, in revenue related to the research contract in recognition of the proportional performance achieved by the Company. Total revenue recognized on the contract from inception through December 31, 2012 was approximately \$1,100,000.

### *Revenue Arrangements with Multiple Deliverables*

The Company occasionally enters into revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using VSOE of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect the Company's results of operations.

The Company expects to periodically receive license fees for non-exclusive research licensing associated with funded research projects. License fees under these arrangements are recognized over the term of the contract or development period as it has been determined that such licenses do not have stand-alone value.

### *NIH and U.S. Treasury Grant Revenues*

During 2010, the U.S. Treasury awarded the Company two one-time grants totaling approximately \$397,000 for investments in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The grants cover reimbursement for qualifying expenses incurred by the Company in 2010 and 2009. The proceeds from these grants are classified in Revenues - Grants for the period from inception through December 31, 2012.

During 2012, 2010 and 2009, the NIH awarded the Company three research grants totaling approximately \$558,000. Revenues from the NIH grants are based upon internal and subcontractor costs incurred that are specifically covered by the grants, and where applicable, an additional facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors and as the Company incurs internal expenses that are related to the grants. Revenue recognized under these grants for the years ended December 31, 2012 and 2011 was approximately \$162,000 and \$57,000,

## **Table of Contents**

respectively. Total revenue recorded under these grants from inception through December 31, 2012 was approximately \$430,000.

### *Stock-based compensation*

The Company accounts for stock-based compensation in accordance with the Financial Accounting and Standards Board's ASC Topic 718, *Compensation - Stock Compensation*, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at their estimated fair value as they vest.

### *Comprehensive income (loss)*

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). For the years ended December 31, 2012 and 2011, and for the period April 19, 2007 (inception) through December 31, 2012, the comprehensive loss was equal to the net loss.

### *Net loss per share*

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under restricted stock units, shares subject to repurchase and warrants as the effect would be anti-dilutive. No dilutive effect was calculated for the year ended December 31, 2012 or 2011 as the Company reported a net loss for each respective year and the effect would have been anti-dilutive. Total common stock equivalents that were excluded from computing diluted net loss per share were approximately 14.1 million and 5.3 million for the years ended December 31, 2012 and 2011, respectively.

### *Reclassifications*

Certain reclassifications were made to the 2011 financial statements in order to conform to the presentation of the 2012 financial statements. The reclassifications did not have any effect on previously reported net loss.

### *New accounting standards*

In June 2011, FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This ASU presents an entity with the option to present the total of comprehensive income, the components of net income, and the component of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of other comprehensive income along with a total for other comprehensive income, and a total amount for

**Table of Contents**

comprehensive income. This update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity/deficit. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other Comprehensive income must be reclassified to net income. ASU No. 2011-05 should be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company's adoption of this standard in 2012 had no effect on presentation of the consolidated financial statements for the years ended December 31, 2012 or 2011, or for the period from April 19, 2007 (inception) to December 31, 2012, as the Company did not have other comprehensive income for the respective periods.

**2. Fixed Assets**

Fixed assets consisted of the following (in thousands):

December 31,	2012	2011
Laboratory equipment	\$ 759	\$ 345
Leasehold improvements		34
Computer software and equipment	114	28
Furniture and fixtures	33	19
	906	426
Less accumulated depreciation and amortization	(192)	(148)
	\$ 714	\$ 278

Depreciation and amortization expense for the years ended December 31, 2012 and 2011 was approximately \$188,000 and \$63,000, respectively. Depreciation and amortization expense was approximately \$336,000 for the period from April 19, 2007 (inception) through December 31, 2012.

**3. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

December 31,	2012	2011
Accrued compensation	\$ 720	\$ 317
Other accrued expenses	73	92
Deferred rent	188	29
	\$ 981	\$ 438

**4. Derivative Liability**

During 2012, in relation to the reverse Merger and the three offerings under the Private Placement, the Company issued 21,347,182 five-year warrants to purchase the Company's common stock. In October and November of 2011, the Company issued 1,500,000 five-year warrants in connection with Convertible Notes. The exercise price of the warrants is protected against down-round financing throughout the term of the warrant, as described below. Pursuant to ASC 815-15 and ASC 815-40, the fair value of the warrants of approximately \$32.7 million and \$1.3 million in 2012 and 2011, respectively, was recorded as a derivative liability on the issuance dates.

**Table of Contents**

The Company revalued the warrants at the end of 2012 and 2011, and the estimated fair value of the outstanding warrant liabilities was \$20.6 million and \$1.3 million at December 31, 2012 and 2011, respectively. The change in fair value of the derivative liabilities for the years ended December 31, 2012 and 2011 was an increase of \$9.9 million and less than \$0.1 million, respectively, and is included in other income (expense) in the statements of operations.

During the year ended December 31, 2012, 13,010,237 warrants that were classified as derivative liabilities were exercised. The warrants were revalued as of the settlement date, and the change in fair value was recognized to earnings. The Company also recognized a reduction in the warrant liability based on the fair value as of the settlement date, with a corresponding increase in additional paid-in capital.

The derivative liabilities were valued at the closing dates of the Private Placement and the end of each reporting period using a Monte Carlo valuation model with the following assumptions:

	December 31, 2011	December 31, 2012
Closing price per share of common stock	\$ N/A	\$ 2.60
Exercise price per share	\$ 1.00	\$ 1.00
Expected volatility	109.8%	92.9%
Risk-free interest rate	0.83%	0.54%
Dividend yield		
Remaining expected term of underlying securities (years)	5.00	4.16

In addition, as of the valuation dates, management assessed the probabilities of future financings assumptions in the Monte Carlo valuation models. Management also applied a discount for lack of marketability to the valuation of the derivative liabilities based on such trading restrictions due to the shares not being registered.

In accordance with the terms of the warrant agreements, if, prior to the expiration date of the warrants, the Company issues additional shares of common stock, as defined below, without consideration or for a consideration per share less than the exercise price of the warrants in effect immediately prior to such issue, then the exercise price shall be reduced, concurrently with such issue, to a price (calculated to the nearest cent) determined by multiplying such exercise price by a fraction, (A) the numerator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issue plus (2) the number of shares of common stock which the aggregate consideration received or to be received by the Company for the total number of additional shares of common stock so issued would purchase at such exercise price; and (B) the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issue plus the number of such additional shares of common stock so issued; provided that (i) all shares of common stock issuable upon conversion or exchange of convertible securities outstanding immediately prior to such issue shall be deemed to be outstanding, and (ii) the number of shares of common stock deemed issuable upon conversion or exchange of such outstanding convertible securities shall be determined without giving effect to any adjustments to the conversion or exchange price or conversion or exchange rate of such convertible securities resulting from the issuance of additional shares of common stock that is the subject of this calculation. For purposes of the warrants, additional shares of common stock shall mean all shares of common stock issued by the Company after the effective date (including without limitation any shares of common stock issuable upon conversion or exchange of any convertible securities or upon exercise of any option or warrant, on an as-converted basis), other than: (i) shares of common stock (and/or warrants for any class of equity securities of the Company) issued or issuable upon conversion or exchange of any convertible securities or exercise of any options or warrants outstanding on the effective date; (ii) shares of common stock issued or issuable by reason of a dividend, stock split, split-up or other distribution on shares of common stock; (iii) shares of common stock (or options with respect thereto) issued or issuable to employees or directors of, or consultants to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Company; (iv) any securities issued or issuable by the Company pursuant to (A) the Private Placement; or (B) the Merger; (v) securities issued pursuant to acquisitions or strategic transactions approved by a majority of disinterested

**Table of Contents**

directors of the Company, provided that any such issuance shall only be to a person which is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company and in which the Company receives benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities and (vi) securities issued to financial institutions, institutional investors or lessors in connection with credit arrangements, equipment financings or similar transactions approved by a majority of disinterested directors of the Company, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

Upon each adjustment of the exercise price pursuant to the provisions stated above, the number of warrant shares issuable upon exercise of the warrants shall be adjusted by multiplying a number equal to the exercise price in effect immediately prior to such adjustment by the number of warrant shares issuable upon exercise of the warrant immediately prior to such adjustment and dividing the product so obtained by the adjusted exercise price.

**5. Convertible Notes Payable***Convertible notes*

From February 9, 2008 through December 31, 2011 the Company raised an aggregate of \$2,390,000 in funds through loans consisting of convertible notes ( Convertible Notes ) to certain shareholders, management, vendors, and investors. The notes bore interest at rates ranging from 8% to 10% per annum and had maturity dates ranging from 2011 to 2018. The Convertible Notes were unsecured and subordinated to certain senior indebtedness of the Company, and for all Convertible Notes the principal plus accrued interest was convertible into the Company's Common stock. During October 2011, in connection with the Exchange Agreement and Release, the Convertible Notes and accrued interest converted into the Company's common stock.

*Local Bridge*

During July and August 2011, \$740,000 of Convertible Notes bearing interest at 20% per annum, and warrants to purchase shares of common stock were issued to investors. The Convertible Notes were due at the earlier of 1) one year from the issuance date or 2) one week after the consummation of a Merger transaction. The number of warrants to be issued was equal to the note principal divided by the exercise price. The exercise price was the per share or per unit fair market value received in the Merger. The notes were convertible at a price per share equal to seventy-five percent (75%) of the per share fair market value of the total consideration received for a share of a public company's common stock to be determined to be identified upon consummation of a merger.

The Company determined that the beneficial conversion feature and the warrants did not represent embedded derivative instruments. Additionally, the Company did not record the discount for the beneficial conversion feature due to the contingencies surrounding conversion. The beneficial conversion feature was recorded when the contingencies were resolved. In accordance with ASC 470-20, Debt with Conversion and Other Options, the Company recorded a discount of approximately \$583,700 for the warrants. The discount was amortized to interest expense over the term of the Convertible Notes using the effective interest method.

The Company calculated the fair value of the warrants using the Black-Scholes Model using a volatility of 109.84%, an interest rate of 1.12% and a dividend yield of zero. Certain of these Convertible Notes and accrued interest were converted into the Company's common stock in October 2011, in connection with the Exchange Agreement and Release, as discussed below. Upon conversion the Company recognized the unamortized debt discount related to these notes to interest expense. The Company recognized approximately \$583,700 of interest expense for the amortization of the note discount during the year ended December 31, 2011.

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**Table of Contents**

*Exchange agreement and Release*

In October 2011, the Company's Board of Directors and shareholders approved an Exchange Agreement, whereby the note holders could exchange their Convertible Notes and accrued interest for shares of the Company's common stock and warrants to purchase the Company's common stock. A total of \$3,030,000 of principal and approximately \$459,800 of accrued interest converted, at prices ranging from \$0.27 to \$0.75, into 7,676,828 shares of the Company's common stock, plus five-year warrants to purchase 1,309,750 common shares at an exercise price of \$1.00 per share. For the holders that elected to participate, the Exchange Agreement and Release resulted in the cancellation of the Convertible Notes and release from the note holders for any claims related to the Convertible Notes.

The Company determined that the warrants issued in connection with the Exchange Agreement and Release did not represent derivative instruments. The warrants, valued at approximately \$527,600, were classified as equity instruments and recorded as interest expense on the date of issuance in 2011. The Company calculated the fair value of the warrants using the Black-Scholes Model, using a volatility of 110.13%, an interest rate of 1.11% and a dividend yield of zero.

At December 31, 2011, an unsecured \$100,000 Convertible Note, with interest at 10% and a maturity date of April 2014, remained outstanding. In February 2012, at the close of the Merger, the convertible note and accrued interest in the aggregate of approximately \$110,000 were repaid.

*2011 Private placement*

On September 18, 2011, Organovo, Inc.'s Board of Directors authorized a private placement offering of up to 30 Units of its securities at a price of \$50,000 per Unit for an aggregate purchase price of \$1,500,000. Each Unit consisted of a convertible note in the principal amount of \$50,000 accruing simple interest at the rate of 6% per annum (the Convertible Notes), plus five-year warrants to purchase 50,000 shares of the next Qualified Round of Equity Securities, at an exercise price of \$1.00 per share. The principal plus accrued interest was convertible into the Company's common stock upon consummation of the Merger.

During October and November 2011, \$1,500,000 of Convertible Notes bearing interest at 6% per annum with a maturity date of March 30, 2012, and five-year warrants to purchase 1,500,000 shares of the Company's common stock were issued to investors under the Private Placement. The warrants are exercisable at \$1.00 per share, expire in five years, and contain down-round price protection. The Convertible Notes were outstanding at December 31, 2011, and were converted into 1,525,387 Units during February 2012, in connection with the Merger.

The Company determined that the warrants represent a derivative instrument due to the down-round price protection, and accordingly, the Company recorded a derivative liability related to the warrants, with a corresponding debt discount of approximately \$1,260,300. See Note 4. Additionally, upon issuance of the notes during 2011, the Company recorded the discount for the beneficial conversion feature of \$239,700. The debt discount associated with the warrants and beneficial conversion feature were amortized to interest expense over the life of the Convertible Notes, and fully amortized upon conversion of the Convertible Notes. The Company recorded approximately \$896,200 and \$603,800 of interest expense for the amortization of the debt discount during the years ended December 31, 2012 and 2011, respectively, and approximately \$1,500,000 for the period from inception through December 31, 2012.

As consideration for locating investors to participate in the Private Placement, the placement agent earned a cash payment of \$195,000 in 2011. Additionally, upon closing of the Merger transaction in 2012, the placement agent earned five-year warrants to purchase 610,155 shares of the Company's common stock at \$1.00 per share. These warrants contain down round protection and were classified as derivative liabilities upon issuance. See Note 4.

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**Table of Contents**

*2012 Private placement*

During 2012, concurrently with the closing of the Merger and in contemplation of the Merger, the Company completed the initial closing of the Private Placement of up to 8,000,000 Units of its securities, at a price of \$1.00 per Unit, with the ability to increase the offering to an aggregate of up to 16,000,000 Units. Each Unit consisted of one share of common stock and a warrant to purchase one share of common stock. The Company completed three closings under the Private Placement during 2012, and raised total gross proceeds of \$13,722,600 and total net proceeds of \$11,593,066. The Company issued 13,722,600 shares of its common stock and warrants to purchase 15,247,987 shares of its common stock (including warrants to purchase 1,525,387 shares to former holders of the bridge notes) exercisable at \$1.00 to investors in the Offering. The placement agent and its selected dealers were paid total cash commissions of \$1,372,260 and the placement agent was paid an expense allowance of \$411,678 and was issued placement agent warrants to purchase 6,099,195 shares of the Company's common stock at an exercise price of \$1.00 per share.

The warrants issued to the investors and the placement agent, as described above, contain down round protection, and accordingly, were classified as derivative liabilities upon issuance. On the closing date, the derivative liabilities were recorded at an estimated fair value of approximately \$32,742,000. Given that the fair value of the derivative liabilities exceeded the total proceeds of the private placement of \$13,722,600, no net amounts were allocated to the common stock. The amount by which the recorded liabilities exceeded the proceeds of approximately \$19,019,400 was charged to other expense at the closing dates. The Company has revalued the derivative liability as of December 31, 2012, and will continue to do so on each subsequent balance sheet date until the securities to which the derivative liabilities relate are exercised or expire, with any changes in the fair value recognized through earnings in the statement of operations. See Note 4.

Interest expense, including amortization of the note discounts was approximately \$1,088,000 and \$2,067,000 for the years ended December 31, 2012 and December 31, 2011, respectively. Interest expense, including amortization of the note discounts, for the period from April 19, 2007 (inception) through December 31, 2012 was approximately \$3,406,000.

*Registration rights agreement*

The Company entered into a registration rights agreement ( *Registration Rights Agreement* ) with the investors in the Offering. Under the terms of the Registration Rights Agreement, the Company agreed to file a registration statement covering the resale of the common stock underlying the Units and the common stock that is issuable on exercise of the Investor Warrants (but not the common stock that is issuable upon exercise of the warrants issued as compensation to the placement agent in connection with the Offering) within 90 days from the final closing date of the Offering (the *Filing Deadline* ). The Company filed the registration statement on June 13, 2012. The registration statement became effective during July 2012.

The Company agreed to use reasonable efforts to maintain the effectiveness of the registration statement through the one year anniversary from the date the registration statement was declared effective by the Securities and Exchange Commission (the *SEC* ), or until Rule 144 of the 1933 Act is available to investors in the Offering with respect to all of their shares, whichever is earlier. If the Company had not met the Effectiveness Deadline, the Company would have been liable for monetary penalties equal to one-half of one percent (0.5%) of each investor's investment in the offering at the end of every 30 day period following such Effectiveness Deadline failure until such failure was cured. No payments shall be owed with respect to any period during which all of the investor's registrable securities may be sold by such investor under Rule 144 or pursuant to another exemption from registration.

## **Table of Contents**

### **6. Stockholders' Equity**

#### *Common stock*

In October 2011, the Company issued 7,676,828 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$3,030,000 and accrued interest totaling approximately \$459,800.

During February and March 2012, the Company issued 21,247,987 shares of common stock related to the Merger. See Note 1. During the year ended December 31, 2012, the Company issued 13,423,622 shares of common stock upon exercise of 13,532,487 warrants.

During the year ended December 31, 2012, 224,064 stock options were exercised for 224,064 shares of common stock.

#### *Restricted stock awards*

In February 2008, four founders, including the Chief Executive Officer ( CEO ) and three directors of the Company received 11,779,960 shares of restricted common stock, 25% vesting after the first year and the remaining 75% vesting in equal quarterly portions over the following three years. These shares are fully vested as of December 31, 2012.

In May of 2008, the Board of Directors of the Company approved the 2008 Equity Incentive Plan (the 2008 Plan ). The 2008 Plan authorized the issuance of up to 1,521,584 common shares for awards of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminates on July 1, 2018. No shares were issued under the 2008 Plan during 2012, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

From 2008 through December 31, 2011, the Company issued a total of 1,258,934 shares of restricted common stock to various employees, advisors, and consultants of the Company. Of those shares, 1,086,662 were issued under the 2008 Plan and the remaining 172,272 shares were issued outside the plan.

In January of 2012, the Board of Directors of the Company approved the 2012 Equity Incentive Plan (the 2012 Plan). The 2012 Plan authorized the issuance of up to 6,553,986 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares, and other stock or cash awards. The 2012 Plan terminates ten years after its adoption.

During the year ended December 31, 2012, the Company issued an aggregate 950,000 of restricted stock units to certain members of senior management and 230,000 restricted stock units to non-executive employees. The vesting schedule is 25% on the anniversary of the vesting start date over four years.

During the year ended December 31, 2012, the Company issued an aggregate 200,000 restricted stock units to certain members of senior management, the vesting of which is performance based. As of December 31, 2012, the Company believes the financial targets will be met, and accordingly is recognizing the related stock based compensation expense over the requisite service period.

During the year ended December 31, 2012, there were 185,516 shares of restricted stock cancelled. 148,016 of the restricted stock units that were forfeited relate to shares of common stock returned to the Company, at the option of the holders, to cover the tax liability related to the vesting of 211,250 restricted stock units. Upon the return of the common stock, 83,986 stock option grants with immediate vesting, were granted to the individuals at the vesting date market value strike price. The remaining 37,500 restricted stock units were forfeited by one staff member upon termination of their employment with the company.



**Table of Contents**

A summary of the Company's restricted stock award activity is as follows:

	<b>Number of Shares</b>
Unvested at December 31, 2007	
Granted	12,627,697
Vested	(65,211)
Canceled / forfeited	
Unvested at December 31, 2008	12,562,486
Granted	130,422
Vested	(5,373,004)
Canceled / forfeited	
Unvested at December 31, 2009	7,319,904
Granted	219,369
Vested	(3,256,191)
Canceled / forfeited	
Unvested at December 31, 2010	4,283,082
Granted	61,406
Vested	(3,233,193)
Canceled / forfeited	
Unvested at December 31, 2011	1,111,295
Granted	1,380,000
Vested	(1,143,735)
Canceled / forfeited	(185,516)
Unvested at December 31, 2012	1,162,044

The fair value of each restricted common stock award is recognized as stock-based expense over the vesting term of the award. The Company recorded restricted stock-based compensation expense in operating expenses for employees and non-employees of approximately \$834,000 and \$3,000 during the years ended December 31, 2012 and 2011, respectively. The Company recorded restricted stock-based compensation expense of approximately \$854,000 for the period from April 19, 2007 (inception) through December 31, 2012.

As of December 31, 2012, total unrecognized restricted stock-based compensation expense was approximately \$1,400,000, which will be recognized over a weighted average period of 2.85 years.

*Stock options*

Under the 2008 Equity Incentive Plan, on October 12, 2011, the Company granted an officer incentive stock options to purchase 896,256 shares of common stock at an exercise price of \$0.08 per share, a quarter of which vested on the one year anniversary of employment, in May 2012, and the remaining options will vest ratably over the remaining 36 month term. Other than this grant, the Company does not intend to issue any additional shares under the 2008 Plan.

During the year ended December 31, 2012 under the 2012 Equity Incentive Plan, 2,023,394 incentive stock options were issued, at various exercise prices, a quarter of which will vest on either the one year anniversary of employment or one year anniversary of the vesting commencement date. The remaining options will vest ratably over the remaining 36 month terms, with the exception of 83,986 of the incentive stock option grants that have immediate vesting at the grant date and 124,000 of the incentive stock option grants that vest quarterly over three years.



**Table of Contents**

The following table summarizes stock option activity for 2011 and 2012:

	Options Outstanding	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2010			
Options granted	896,256	\$ 0.08	
Options canceled			
Options exercised			
Outstanding at December 31, 2011	896,256	\$ 0.08	
Options granted	2,023,394	\$ 1.95	
Options canceled	(5,000)	\$ 2.25	
Options exercised	(224,064)	\$ 0.08	\$ 564,641
Outstanding at December 31, 2012	2,690,586	\$ 1.48	\$ 3,041,476
Vested and Exercisable at December 31, 2012	96,304	\$ 2.12	\$ 46,335

The weighted-average remaining contractual term of options exercisable and outstanding at December 31, 2012 was approximately 9.7 years and 9.4 years, respectively.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock based compensation expense is recognized over the vesting period using the straight-line method. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	December 31, 2012	December 31, 2011
Dividend yield		
Volatility	96.22%	111.00%
Risk-free interest rate	0.89%	1.07%
Expected life of options	6.05 years	5.0 years
Weighted average grant date fair value	\$ 1.50	\$ 0.06

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Due to the Company's limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury rates. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options.

The total employee stock-based compensation recorded as operating expenses was approximately \$600,000 and \$6,000 for the years ended December 31, 2012 and 2011 respectively. The Company recorded stock-based compensation expense of approximately \$606,000 for the period from April 19, 2007 (inception) through December 31, 2012.

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2012 was approximately \$2,479,000, and the weighted average period over which these grants are expected to vest is 3.3 years.

**Warrants**

During the years ended December 31, 2012 and 2011, the Company issued warrants to investors to purchase 21,347,182 and 2,909,750 shares, respectively, of its common stock. These warrants are immediately exercisable at \$1.00 per share, and have a weighted average remaining term of approximately 4.16 years.



**Table of Contents**

During 2012, 13,259,987 of these warrants were exercised for cash proceeds of \$11,356,251, and 272,500 of these warrants were exercised through a cashless exercise for issuance of 163,635 shares of common stock. No warrants were exercised during 2011.

In December 2012, the Company consummated a Warrant Tender Offer to amend certain of its warrants to purchase approximately 14.5 million shares of the Company's common stock. In accordance with the Tender Offer, for those warrant holders that elected to participate, this resulted in a reduction of the exercise price of the warrants from \$1.00 per share to \$0.80 per share of common stock in cash, shortened the exercise period of the warrants so that they expired concurrently with the tender offer, and removed the price-based anti-dilution provisions contained in the warrants. The Company completed the Tender Offer on December 21, 2012, resulting in approximately 9.6 million warrants exercised for gross proceeds of approximately \$7.7 million. In connection with the transaction, the Company recognized an expense for the inducement to exercise the warrants of approximately \$1.9 million. The Company also incurred approximately \$0.4 million in placement agent fees, legal costs, and other related fees, which have been recognized as an offset to the proceeds received from the warrant exercises.

13,010,237 of the warrants exercised in 2012 were derivative liabilities and were valued at the settlement date. The warrant liability was reduced to equity at the fair value on the settlement date. See Note 4.

Additionally, during the year ended December 31, 2012 the Company entered into four agreements with consultants for services. In connection with the agreements, the Company issued a total of 650,000 warrants to purchase common stock, at prices ranging from \$1.70 to \$3.24, with lives ranging from two to five years, to be earned over service periods of up to six months. The fair value of the warrants was estimated to be approximately \$890,000, which was recognized as a prepaid asset and is being amortized over the term of the consulting agreements. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using volatility rates ranging from 79.8% to 103.8% and risk free interest rate factors ranging from 0.24% to 0.63%, were used to determine the value. The value is being amortized over the term of the agreements. During the year ended December 31, 2012, the Company recognized approximately \$556,000 of expense related to these services.

The following table summarizes warrant activity for the years ended December 31, 2012 and 2011:

	Warrants	Weighted-Average Exercise Price
Balance at December 31, 2010		\$
Granted	2,909,750	\$ 1.00
Expired / Canceled		\$
Exercised		\$
Balance at December 31, 2011	2,909,750	\$ 1.00
Granted	21,997,182	\$ 1.04
Exercised	(13,532,487)	\$ 0.84
Balance at December 31, 2012	11,374,445	\$ 1.08

*Common stock reserved for future issuance*

Common stock reserved for future issuance consisted of the following at December 31, 2012:

Common stock warrants outstanding	11,374,445
Common stock options outstanding under the 2008 Plan	672,192
Common stock options outstanding and reserved under the 2012 Plan	4,651,160
Total	16,697,797



**Table of Contents****7. Commitments and Contingencies***Operating leases*

The Company leases office and laboratory space under non-cancelable operating leases. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent. Deferred rent is included in accrued expenses in the consolidated balance sheets.

Rent expense was approximately \$325,600 and \$145,200 for the years ended December 31, 2012 and 2011, respectively. Rent expense was approximately \$650,200 for the period from April 19, 2007 (inception) through December 31, 2012.

The Company entered into a new facilities lease at 6275 Nancy Ridge Drive, San Diego, CA 92121. The lease was signed on February 27, 2012 with occupancy as of July 15, 2012. The base rent under the lease is approximately \$38,800 per month with 3% annual escalators. The lease term is 48 months with an option for the Company to extend the lease at the end of the lease term.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2012, are as follows (in thousands):

2013	\$ 379
2014	490
2015	503
2016	297
2017	
Total	\$ 1,669

During the year ended December 31, 2012, the Company entered into an agreement to lease certain laboratory equipment under a non-cancelable capital lease, which is included in fixed assets as follows (in thousands):

December 31, 2012	
Lab equipment	\$ 34
Less accumulated depreciation	(3)
Net book value	\$ 31

Depreciation expense related to the capital lease obligation was approximately \$2,900, for the year ended December 31, 2012.

Future minimum capital lease payments at December 31, 2012 are as follows (in thousands):

Year Ending December 31,	
2013	\$ 11
2014	11
2015	7
Total minimum lease payments	29
Amount representing interest	(2)
Present value of minimum lease payments	27

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Less current portion	(10)
Long term portion	\$ 17

F-25



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**Table of Contents****8. Licensing Agreements and Research Contracts***University of Missouri*

On March 24, 2009, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to self-assembling cell aggregates and to intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company paid to the University of Missouri a nonrefundable license fee of \$25,000 and has committed to reimburse the University of Missouri for certain prior and future patent costs. Each year the Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales depending on the level of net sales achieved by the Company each year. A minimum annual royalty of \$25,000 is due beginning 2 years after the calendar year of the first commercial sale and is credited to sales royalties. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement, which are expected to expire after 2029. The \$25,000 license fee is included in Other Assets in the accompanying balance sheets and is being amortized over the life of the related patent.

On March 12, 2010, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to engineered biological nerve grafts. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company paid to University of Missouri a nonrefundable license fee of \$5,000 and has committed to reimburse the University of Missouri for certain prior and future patent costs. In 2012 and 2011, the Company paid the University of Missouri approximately \$193,500 and \$23,800, respectively, for prior patent costs relating to the license agreements with the University of Missouri. Each year the Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales depending on the level of net sales achieved by the Company each year. A minimum annual royalty of \$5,000 is due beginning 2 years after the calendar year of the first commercial sale and is credited to sales royalties. An additional royalty of \$12,500 is due if there are no net sales within five years from the effective date of the license. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement. The \$5,000 license fee is included in Other Assets and is being amortized over the life of the related patent.

*Clemson University*

On May 2, 2011, the Company entered into a license agreement with Clemson University Research Foundation to in-license certain technology and intellectual property relating to ink-jet printing of viable cells. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company agreed to pay Clemson University a nonrefundable license fee of \$32,500, as well as an additional \$32,500 to reimburse Clemson University for certain prior and future patent costs. These fees, totaling \$65,000, are included in Other Assets and are being amortized over the life of the related patent. Each year the Company is required to pay the University royalties ranging from 1.5% to 3% of net sales depending on the level of net sales reached each year and minimum annual fees ranging from \$20,000 to \$40,000. Specific terms of the royalty and license agreements are confidential. The license agreement terminates upon expiration of the patents licensed, which is expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement.

No royalty payments have been made under the above license agreements as of December 31, 2012. Approximately \$4,000 will be due to the University of Missouri in 2013 relating to the first commercial sale. Annual royalty payments of \$25,000 will be due to the University of Missouri beginning in 2014 per the terms of the respective license agreements.

**Table of Contents**

Capitalized license fees consisted of the following (in thousands):

<i>December 31,</i>	<b>2012</b>	<b>2011</b>
License fees	\$ 95	\$ 95
Less accumulated amortization	(15)	(8)
<b>License fees, net</b>	<b>\$ 80</b>	<b>\$ 87</b>

Amortization expense of licenses was approximately \$7,000, \$5,200 and \$14,700 for 2012, 2011 and for the period from April 19, 2007 (inception) through December 31, 2012, respectively. At December 31, 2012, the weighted average remaining amortization period for all licenses was approximately 12 years. The annual amortization expense of licenses for the next five years is estimated to be approximately \$7,000 per year.

**9. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets are as follows as of December 31, 2012 and 2011 (in thousands):

<i>December 31,</i>	<b>2012</b>	<b>2011</b>
Deferred tax assets:		
Net operating loss carry forwards	\$	\$ 1,620
Research and development credits		190
Depreciation and amortization	(2)	8
Accrued expenses and reserves	290	107
Stock Compensation	562	
<b>Total deferred tax assets</b>	<b>850</b>	<b>1,925</b>
Valuation allowance	(850)	(1,925)
	<b>\$</b>	<b>\$</b>

A full valuation allowance has been established to offset the deferred tax assets as management cannot conclude that realization of such assets is more likely than not. Under the Internal Revenue Code ( IRC ) Sections 382 and 383, annual use of our net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. We have not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2012. Until this analysis is completed, we have removed the deferred tax assets related to net operating losses and research credits from our deferred tax asset schedule and recorded a corresponding decrease to the valuation allowance. As a result, the valuation allowance decreased by approximately \$1,075,000 during 2012.

At December 31, 2012, the Company had federal and state net operating loss carryforwards of approximately \$11,867,000 and \$11,863,000, respectively. The federal and state net operating loss carryforwards will begin expiring in 2028, unless previously utilized.

At December 31, 2012, the Company had federal and state research tax credit carryforwards of approximately \$112,000 and \$252,000, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

In 2009 the Company adopted the accounting guidance for uncertainty in income taxes pursuant to ASC 740-10. The adoption of this guidance did not have a material impact on the Company's consolidated financial

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## **Table of Contents**

statements. The Company did not record any accruals for income tax accounting uncertainties for the years ended December 31, 2012 or 2011.

The Company's policy is to recognize interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits as a component of income tax expense. The Company did not accrue either interest or penalties as of December 31, 2012 or 2011.

The Company is subject to tax in the United States and in the state of California. As of December 31, 2012, the Company's tax years from inception are subject to examination by the tax authorities. The Company is not currently under examination by any U.S. federal or state jurisdictions.

### **10. Concentrations**

#### *Credit risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions primarily located in San Diego. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. At times, balances may exceed federally insured limits. The Company has not experienced losses in such accounts, and management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

### **11. Subsequent Events**

#### *OHSU Collaboration*

On January 4, 2013, the Company entered into a collaboration agreement with the Knight Cancer Institute at Oregon Health & Science University ( OHSU ), a national leader in translational oncology research, to develop more clinically predictive *in vitro* three dimensional cancer models which are ultimately expected to advance discovery of novel cancer therapeutics.

#### *Warrant redemption*

On February 5, 2013, the Company announced its intention to redeem one class of outstanding warrants initially issued to investors participating in private placement financings in 2011 and 2012. The warrant redemption was intended to raise non-dilutive capital, enable the Company to significantly improve its balance sheet, help position the Company to qualify to list its common stock on the NYSE MKT or NASDAQ exchange, and decrease a significant portion of the derivative liability from its balance sheet.

A Notice of Redemption was mailed to affected warrant holders on February 5, 2013. These warrant holders had until 5:00 p.m. ET on March 14, 2013, to exercise their outstanding warrants at \$1.00 per share. Thereafter, any warrants that remained unexercised would have automatically been redeemed by the Company at a redemption price of \$0.0001 per share of common stock then issuable upon exercise of the redeemed warrant. Approximately 2.4 million warrant shares are affected by this Notice of Redemption. As of March 14, 2013, 2.4 million shares were redeemed for total proceeds of approximately \$2.3 million.

Previously, on December 21, 2012, the Company completed a tender offer including the same warrants. At that time, approximately two-thirds of warrant holders elected to participate in the tender offer and exercised their warrants at \$0.80 per share. The Notice of Redemption was given to the remaining warrant holders at the Company's option following the qualifying event of its common stock trading at \$2.50 per share or higher for twenty (20) consecutive trading days. All affected warrant holders elected to exercise their warrants prior to the redemption date. Approximately \$2.4 million of additional equity capital was raised by the Company without any increase to its fully diluted shares. If none of the warrant holders exercised their warrants prior to the redemption date the Company would have redeemed and canceled all affected warrants at an aggregate cost of approximately \$293. As of March 14, 2013, all redeemable warrants had been exercised.

## **Table of Contents**

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed pursuant to the Securities Exchange Act of 1934, as amended (the Exchange Act) is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Under the supervision of our Chief Executive Officer and our Chief Financial Officer, and with the participation of all members of management, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were designed and operating effectively as of the end of the period covered by this Form 10-K.

#### **Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### ***Inherent Limitations on Effectiveness of Controls***

Our management, including our Chief Executive Officer and our Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

### **Item 9B. Other Information.**

Not applicable.

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

The following persons are our directors and executive officers and hold the positions set forth opposite their names as of March 1, 2013.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Keith Murphy	41	Chairman of the Board, Chief Executive Officer and President
Robert Baltera	47	Director
Andras Forgacs	36	Director
James Glover	63	Director
Adam Stern	48	Director
Barry Michaels	63	Chief Financial Officer and Corporate Secretary
Sharon Presnell	44	Chief Technology Officer and Executive Vice President of Research and Development
Eric David	41	Chief Strategy Officer
Michael Renard	54	Executive Vice President of Commercial Operations

**Keith Murphy, Chairman of the Board, Chief Executive Officer and President**, is one of our founders and joined us in July 2007. Mr. Murphy was formerly an employee of biotechnology company Alkermes, Inc., where he worked from July, 1993 to July, 1997 and played a role on the development team for their first approved product, Nutropin (hGH) Depot. He moved to Amgen, Inc. in August, 1997 and developed several other novel formulation and device products. He has over 19 years of experience in biotechnology, including serving in Product Strategy and Director of Process Development roles at Amgen through July, 2007. He was previously Global Operations Leader for the largest development program in Amgen's history, osteoporosis/bone cancer drug Prolia/Xgeva (denosumab). He holds a BS in Chemical Engineering from MIT, and is an alumnus of the UCLA Anderson School of Management.

Mr. Murphy's previous experience in the biotechnology field and his educational experience qualify him to be a member of our Board of Directors.

**Robert Baltera, Jr., Director**, joined us as a director in October, 2009. Most recently, Mr. Baltera was the Chief Executive Officer of Amira Pharmaceuticals, a position he held from July, 2007 through September, 2011. Amira was sold to Bristol-Myers Squibb in September, 2011 for \$325 million in cash up front, plus additional milestone payments of up to \$150 million. Mr. Baltera is a seasoned pharmaceutical industry executive who has acquired a wealth of business and product management experience during his 17 years with biotech pioneer Amgen, beginning November, 1990. In his role leading Amira Pharmaceuticals, he was instrumental in focusing the company's development efforts, strengthening and developing its pipeline and forging key collaborations with partners such as GlaxoSmithKline. Before becoming Amira's CEO, he held a number of senior management positions at Amgen, the last being Vice President of Corporate and Contract Manufacturing. He served as Amgen's team leader responsible for the approval of Kinerevin rheumatoid arthritis. Mr. Baltera has an MBA from the Anderson School at UCLA and earned his bachelor's degree in microbiology and a master's degree in genetics from The Pennsylvania State University.

Mr. Baltera's previous experience in the biotechnology field and his educational experience qualify him to be a member of our Board of Directors.

**Andras Forgacs, Director**, is one of our founders and joined us as a director in April, 2007. Mr. Forgacs has served as Chief Executive Officer of Modern Meadow, a private company focused on applying the latest advances in tissue engineering to develop cultured leather and meat products, since August 2011. Mr. Forgacs served as a Managing Director at Richmond Global, an international technology-focused venture fund from

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**Table of Contents**

July, 2008 to January 2012. In his role at Richmond, Mr. Forgacs focuses on the day-to-day management of the fund and the sourcing of new investment opportunities. Prior to joining Richmond, beginning in November, 2005, he was a consultant in the New York office of McKinsey & Company advising global financial institutions, healthcare/pharmaceutical companies and private equity/venture capital firms. Mr. Forgacs began his career with Citigroup as an investment banker in the Financial Strategy Group in July, 1999, and helped found the client-facing E-commerce Group. Mr. Forgacs is a Kauffman Fellow with the Center for Venture Education and a Term Member with the Council on Foreign Relations. He holds an MBA from the Wharton School of Business and a Bachelor of Arts with honors from Harvard University. Mr. Forgacs is the son of Gabor Forgacs, Ph.D., who developed Organovo's breakthrough organ printing technology while leading a team of top regenerative medicine scientists from multiple universities, with the backing of a \$5MM National Science Foundation Grant. Dr. Forgacs was one of the founders of the Company.

Mr. Forgacs' previous experience with start-up companies in the equity/venture capital field and his educational experience qualify him to be a member of our Board of Directors.

**James T. Glover, Director**, joined us in July 2012. Mr. Glover was the Senior Vice President, Operations and Chief Financial Officer of Anadys Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company acquired by Hoffmann-La Roche Inc., from 2006 to 2009. From 1989 to 2006, he was employed by Beckman Coulter, Inc., a leading biomedical testing instruments company, most recently serving as Senior Vice President and Chief Financial Officer. Mr. Glover served as a director of Varian, Inc., a publicly-traded company purchased by Agilent Technologies, and was Varian's audit committee chairman. He currently serves as a director for a non-profit corporation. Mr. Glover received his B.S. in accounting from California State Polytechnic University and his M.B.A. from Pepperdine University. Mr. Glover, age 63, is also a certified public accountant.

Mr. Glover's previous executive officer and Board member experience, including his accounting and financial reporting experience, qualify him to be a member of our Board of Directors.

**Adam K. Stern, Director**, joined us in February 2012 and is the Chief Executive Officer of SternAegis Ventures, and has served as the Head of Private Equity Banking at Aegis Capital Corp. since November 2012. Mr. Stern has over 20 years of venture capital and investment banking experience focusing primarily on the technology and life science sectors of the capital markets. Prior to joining Aegis Capital, he managed the structured finance group of Spencer Trask Ventures, Inc. Mr. Stern joined Spencer Trask Ventures in September 1997 from Josephthal & Co., members of the New York Stock Exchange, where he served as Senior Vice President and Managing Director of Private Equity Marketing and held increasingly responsible positions from 1989 to 1997. He has been a licensed securities broker since 1987 and a General Securities Principal since 1991. Mr. Stern currently sits on the boards of various private companies and one other public company, InVivo Therapeutics Holdings Corp. (OTCBB:NVIV). Mr. Stern holds a Bachelor of Arts degree with honors from The University of South Florida in Tampa.

Mr. Stern's experience as a board member of privately held and publicly traded companies qualifies him to be a member of our Board of Directors. Additionally, his 20 years of venture capital and investment banking focusing on technology and life science sectors will be an asset to the Board of the Directors if we attempt to raise capital in the future.

**Barry D. Michaels, Chief Financial Officer and Corporate Secretary**, joined us in August, 2011. Mr. Michaels was the Chief Financial Officer of Cardima, Inc., a publicly-traded medical device company (NASDAQ: CRDM), from July, 2003 through June, 2005, and thereafter a consultant to the company through January, 2008. Mr. Michaels has been an independent consultant to medical device and technology companies since 1997, and has more than 30 years of combined industry experience. Since January, 2008 and prior to joining us, Mr. Michaels devoted his time to his consulting practice. In addition to his consulting practice, Mr. Michaels served as Chief Financial Officer of Lipid Sciences (NASDAQ: LIPD), a biotechnology company, from May, 2001 through January, 2003. Prior to joining Lipid Sciences, Mr. Michaels served as the Chief Financial Officer of IntraTherapeutics, Inc., an endovascular company, from March, 2000 until its acquisition by Sulzer Medica in May, 2001. Mr. Michaels received an MBA in finance from San Diego State University and is a graduate of the Executive Program at the University of California, Los Angeles.

## **Table of Contents**

**Dr. Sharon Collins Presnell, Chief Technology Officer and Executive Vice President of Research and Development**, joined us in May, 2011. Dr. Presnell has over 15 years of experience in the leadership of product-focused R&D. As an Assistant Professor at the University of North Carolina from 1998 to 2001, Dr. Presnell's research in liver and prostate biology and carcinogenesis produced cell- and tissue-based technologies that were out licensed for industrial applications. She joined Becton Dickinson & Co. (BD) in July, 2001 and played a key role in the early discovery and development of BD's Discovery Platform and FACS CARRools for the optimization of *in vitro* culture environments and flow cytometry-based characterization of cells. In her role at BD, she grew and led a large multi-disciplinary team to establish feasibility for the Discovery Platform and FACS CAP in multiple therapeutic areas, including diabetes, and stewarded both technologies through revenue-generating commercial partnerships. Dr. Presnell joined Tengion, Inc. in February, 2007 as the Senior Vice President of Regenerative Medicine Research, a position that she held until joining us in May 2011. At Tengion, Dr. Presnell was directly involved in the discovery and early development of Tengion's Neo-Kidney Augment technology. Dr. Presnell holds a Ph.D. in Pathology from the Medical College of Virginia.

**Dr. Eric Michael David, Chief Strategy Officer**, joined us in May, 2012. Dr. David was most recently Associate Partner at the consultancy McKinsey & Company, where he served private equity, pharmaceutical, biotech, diagnostic, and medical device clients to support pipeline and R&D strategy, as well as market entry strategy. Dr. David played a critical role in the commercial translation of 3D bioprinting as a founder and early director of Organovo, Inc. Prior to his time at McKinsey, Dr. David served as a freelance consultant to the Department of Health and Human Services in the use of genomic technologies for early detection of pathogens for public health preparedness. He completed his residency in Internal Medicine at New York Presbyterian Hospital, where he served as Assistant Chief Resident and received the Dick Bowman Award for scientific endeavor and dedication to patient care. He was also Assistant Professor at The Rogosin Institute and adjunct faculty at The Rockefeller University. He received his M.D. from Columbia University College of Physicians and Surgeons, his J.D. from Columbia University School of Law, and a B.A. in physics and fine arts from Amherst College. He is board certified in Internal Medicine and admitted to the Bar in New York State.

**Michael Renard, Executive Vice President of Commercial Operations**, joined us in May, 2012. Mr. Renard has more than 29 years of experience in commercial operations, business development and sales and marketing for the life science industry. Since 1997, he has worked with Beckman Coulter holding various positions in program management, business operations and business development. He most recently was the vice president of marketing for North America commercial operations where he was responsible for achieving \$2 billion in revenue across 11 major product lines. Before Beckman Coulter, he was Vice President and General Manager in a start-up development stage incubator division of Sanofi, Inc. and Director of Corporate Accounts at Kallestad Diagnostics. He has an M.B.A from Rockhurst University and a B.A. in biology and chemistry from St. Olaf College.

### **Family Relationships**

Andras Forgacs is the son of Gabor Forgacs, who developed Organovo's breakthrough organ printing technology while leading a team of top regenerative medicine scientists from multiple universities, with the backing of a \$5MM National Science Foundation Grant. Dr. Forgacs was one of the founders of the Company.

### **Corporate Governance**

#### ***Board Composition***

We are not currently listed on any national securities exchange or in an inter-dealer quotation system that has established a standard for independence. However, in evaluating the independence of our members and the composition of the committees of our Board of Directors, our Board utilizes the definition of independence as that term is defined by applicable listing standards of the NASDAQ Stock Market and SEC rules. As of the date of this Annual Report, our Board consists of five members, two of whom are considered independent as that term is defined by applicable listing standards of the NASDAQ Stock Market and SEC rules.

## **Table of Contents**

Our Board of Directors expects to continue to evaluate its independence standards and whether and to what extent the composition of the Board and its committees meets those standards. We ultimately intend to appoint such persons to our Board and committees of our Board as are expected to be required to meet the corporate governance requirements imposed by a national securities exchange. Therefore, we intend that a majority of our directors will be independent directors.

Our Board is divided into three classes. The directors in each class serve three-year terms and in each case until their respective successors are duly elected and qualified. Our Board of Directors, by class, is as follows:

Class I, whose member is Keith Murphy. The terms of the Class I directors expire at our 2015 annual meeting of stockholders;

Class II, whose members are Andras Forgacs and Adam Stern. The terms of the Class II directors expire at our 2013 annual meeting of stockholders; and

Class III, whose members are Robert Baltera and James Glover. The terms of the Class III directors expire at our 2014 annual meeting of stockholders.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of our Board. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the total number of directors. Our directors will hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification, or removal for cause by the affirmative vote of the holders of a majority of the outstanding stock entitled to vote on the election of directors.

### ***Board Leadership Structure***

Our Bylaws provide our Board with flexibility to combine or separate the positions of Chairman of the Board and Chief Executive Officer in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. At the current time, our Chairman of the Board, Keith Murphy, also serves as our Chief Executive Officer and President.

Our Board has concluded that our current leadership structure is appropriate at this time. However, our Board will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### ***Board Committees***

*Compensation Committee.* The Compensation Committee of the Board of Directors currently consists of Messrs. James Glover (Chair), and Robert Baltera. The functions of the Compensation Committee include the approval of the compensation offered to our executive officers and recommending to the full Board of Directors the compensation to be offered to our directors. The Board has determined that Messrs. Glover and Baltera are each an independent director under the listing standards of the NASDAQ Stock Market. In addition, the members of the Compensation Committee qualify as non-employee directors for purposes of Rule 16b-3 under the Exchange Act and as outside directors for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended. The Compensation Committee is governed by a written charter approved by the Board of Directors, a copy of which is available on our website at [www.organovo.com](http://www.organovo.com).



## **Table of Contents**

*Audit Committee.* The Audit Committee of the Board of Directors, currently consists of Messrs. James Glover (Chair) and Robert Baltera. The functions of the Audit Committee include the retention of our independent registered public accounting firm, reviewing and approving the planned scope, proposed fee arrangements and results of the Company's annual audit, reviewing the adequacy of the Company's accounting and financial controls and reviewing the independence of the Company's independent registered public accounting firm. The Board has determined that each current member of the Audit Committee is an independent director under the listing standards of the NASDAQ Stock Market. The Board of Directors has also determined that Mr. Glover is an audit committee financial expert within the applicable definition of the SEC. The Audit Committee is governed by a written charter approved by the Board of Directors, a copy of which is available on our website at [www.organovo.com](http://www.organovo.com).

*Nominating and Corporate Governance Committee.* The Nominating and Corporate Governance Committee of the Board of Directors currently consists of Robert Baltera (chair) and James Glover. The functions of the Nominating and Corporate Governance Committee include the identification, recruitment and nomination of candidates for the Board and its committees, making recommendations to the Board concerning the structure, composition and functioning of the Board and its committees including the reporting channels through which the Board receives information and the quality and timeliness of the information, developing and recommending to the Board corporate governance guidelines applicable to the Company and annually reviewing and recommending changes, as necessary or appropriate, overseeing the annual evaluation of the Board's effectiveness and performance, and periodically conducting an individual evaluation of each director. The Board has determined that each current member of the Nominating and Corporate Governance Committee is an independent director under the listing standards of the NASDAQ Stock Market.

### ***Section 16(a) Beneficial Ownership Reporting Compliance***

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who own more than 10% of our common stock to file reports of ownership and changes in ownership with the SEC. Based solely upon our review of the Forms 3, 4 and 5 filed during 2012, and written representations from certain reporting persons that no Forms 5 were required, we believe that all required reports were timely filed during 2012.

### ***Code of Business Conduct***

We have adopted a code of business conduct that applies to all of our officers, directors, and employees. We will post a copy of our code of business conduct, and intend to post amendments to this code, or any waivers of its requirements, on our website at [www.organovo.com](http://www.organovo.com), as permitted under SEC rules and regulations. The reference to our web address does not constitute incorporation by reference of the information contained at or available through this site.

### ***Consideration of Director Nominees***

In evaluating nominees for membership on our Board, our Nominating and Corporate Governance Committee applies the Board membership criteria set forth in our corporate governance guidelines. Under these criteria, the committee takes into account many factors, including an individual's business experience and skills (including skills in core areas such as operations, management, technology, accounting and finance, strategic planning and international markets), as well as independence, judgment, knowledge of our business and industry, professional reputation, leadership, integrity and ability to represent the best interests of the Company's stockholders. In addition, the Nominating and Corporate Governance Committee will also consider the ability to commit sufficient time and attention to the activities of the Board, as well as the absence of any potential conflicts with the Company's interests. The Nominating and Corporate Governance Committee does not assign specific weights to particular criteria and no particular criterion is necessarily applicable to all prospective nominees. The Board does not have a formal policy with respect to diversity of nominees. Rather, our Nominating and Corporate Governance Committee considers Board membership criteria as a whole and seeks to achieve diversity of occupational and personal backgrounds on the Board. Our Board will be responsible for

**Table of Contents**

selecting candidates for election as directors based on the recommendation of the Nominating and Corporate Governance Committee.

Our Nominating and Corporate Governance Committee regularly assesses the appropriate size of our Board, and whether any vacancies on our Board are expected due to retirement or otherwise. In the event that vacancies are anticipated, or otherwise arise, the committee will consider various potential candidates who may come to the attention of the committee through current Board members, professional search firms, stockholders or other persons. Each candidate brought to the attention of the committee, regardless of who recommended such candidate, is considered on the basis of the criteria set forth in our corporate governance guidelines.

As stated above, our Nominating and Corporate Governance Committee will consider candidates proposed for nomination by our stockholders. Stockholders may propose candidates by submitting the names and supporting information to: Corporate Secretary, 6275 Nancy Ridge Drive, Suite 110, San Diego, CA 92121. Supporting information should include (a) the name and address of the candidate and the proposing stockholder, (b) a comprehensive biography of the candidate and an explanation of why the candidate is qualified to serve as a director taking into account the criteria identified in our corporate governance guidelines, (c) proof of ownership, the class and number of shares, and the length of time that the shares of our voting securities have been beneficially owned by each of the candidate and the proposing stockholder, and (d) a letter signed by the candidate stating his or her willingness to serve, if elected.

**Item 11. Executive Compensation.**

The following table sets forth information regarding each element of compensation that we paid or awarded to our named executive officers and for the years ended December 31, 2012 and 2011.

**EXECUTIVE COMPENSATION TABLE**

Name and Principal Position	Year	Salary \$	Bonus	Option	Stock Awards (\$)	Deferred Compensation (\$)	All Other Compensation (\$)	Total (\$)
			(3) \$	Awards (4) (\$)				
Keith Murphy Chief Executive Officer and President	2012	307,347	30,000		340,000			677,347
	2011	217,711					(1)	217,711
Barry Michaels Chief Financial Officer and Corporate Secretary	2012	250,736	25,000	234,432	1,275,000			1,785,168
	2011	74,315					(2)	74,315
Sharon Presnell Chief Technical Officer	2012	262,836	50,000	303,996				616,832
	2011	157,385		3,163			24,681(2)	185,229
Eric David Chief Strategy Officer	2012	160,968	22,500	761,401			28,245	973,114
Michael Renard Executive Vice President of Commercial Operations	2012	156,927		761,401			40,000	958,328

(1) Excludes payments made for the reimbursement of medical insurance premiums and a personal computer used primarily for business in the aggregate of less than \$10,000.

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**Table of Contents**

- (2) Excludes payments made for the reimbursement of medical insurance premiums.
- (3) Annual bonuses are granted after the completion of each calendar year at the Compensation Committee's discretion, taking into account the Company's performance against corporate goals.
- (4) These amounts represent the grant date fair value of equity-based awards granted by the Company during the years presented, determined in accordance with FASB ASC Topic 718. All awards are amortized over the vesting life of the award.

***Narrative Discussion of the Summary Compensation Table.*** The Compensation Committee of the Board of Directors, which is comprised solely of independent directors, has the responsibility for evaluating and authorizing the compensation payable to the Company's executive officers. In July 2012, the Compensation Committee retained Compensia, Inc., a national compensation consulting firm (Compensia), to provide it with competitive market data and analysis regarding the compensation elements offered to the Company's executive officers, including base salary, cash incentives and equity incentives. Compensia provided the analysis based on a peer group of life science companies approved by the Compensation Committee. The Compensation Committee, based on the data and analysis received from Compensia, adopted and approved the compensation program for its executive officers described below.

**Salary.** The Compensation Committee set the base salaries for the Company's executive officer. The amounts included in the Salary column of the Summary Compensation Table reflect the salary increases approved in July 2012 by the Compensation Committee and are pro-rated for that portion of a year the executive officer actually provided service to the Company.

**Bonus.** The amounts included in the Bonus column in the Summary Compensation Table reflect discretionary bonus payments made during 2012 to Messrs. Murphy and Michaels and Ms. Presnell based on their services during fiscal 2011 and a signing bonus payment made to Mr. David upon his acceptance of employment with the Company.

In July 2012, the Compensation Committee adopted an annual incentive plan, which provides executive officers an incentive opportunity as a percent of base salary upon the achievement of corporate performance goals approved by and evaluated by the Compensation Committee. The Compensation Committee determined that each named executive officer's annual incentive base, target and stretch bonus opportunity expressed as a percentage of base salary would be equal to 15%, 30% and 45% of the executive officer's base salary, respectively, subject to satisfaction of the applicable performance criteria required for the achievement of the base, target and stretch performance levels. The Compensation Committee will have discretion to determine the actual percentage of the annual incentive bonus to award the executives for partial achievement of the performance objectives. For example, if the Company achieves one or more (but not all) of the target performance objectives, the Compensation Committee can award an annual incentive bonus between 15% to 30% of the executive officer's base salary. Following the conclusion of fiscal 2012, the Compensation Committee evaluated the Company's performance and determined that the annual incentive bonus payable to each of the executive officers would be 29.5% of the executive officer's base salary, with the actual payments to be made in fiscal 2013.

In March 2013, the Compensation Committee approved the performance objectives for fiscal 2013 under the annual incentive plan. Similar to 2012, each named executive officer's annual incentive base, target and stretch bonus opportunity for 2013 expressed as a percentage of base salary is equal to 15%, 30% and 45% of the executive officer's base salary, respectively, subject to satisfaction of the applicable performance criteria required for the achievement of the base, target and stretch performance levels.

**Option Awards.** On April 18, 2012, Mr. Michaels and Ms. Presnell were granted options to purchase 62,500 and 175,000 shares of the Company's common stock, respectively, at an exercise price of \$2.25, the closing price of the Company's common stock on the date of grant. On July 23, 2012, Messrs. Renard and David were each granted options to purchase 600,000 shares of the Company's common stock at an exercise price of \$1.65 per

**Table of Contents**

share, the closing price of the Company's common stock on the date of grant. 25% of the option shares vest 12 months from the vesting start date, and the remaining options vest on a quarterly basis over the next 12 quarters (for a total vesting period of 48 months from the date of grant). The vesting of the option shares granted to each of these executive officers will accelerate upon the executive's termination or involuntary termination within 12 months of a change in control of the Company.

**Stock Awards.** On August 6, 2012, Mr. Michaels was granted 750,000 time-based Restricted Stock Units (RSUs) and Mr. Murphy was granted 200,000 time-based RSUs and 200,000 performance based RSUs. The time-based RSUs will vest over four (4) years in equal annual installments with twenty-five percent (25%) vesting after each of the 12th, 24th, 36th, and 48th monthly anniversaries of the vesting start date. The performance-based RSUs will vest upon the Company's achievement of certain performance objectives prior to December 31, 2014, including assuring the Company has adequate working capital to support its business plan, the entry into certain commercial arrangements, the satisfaction of all required qualifications for listing the Company's common stock on one of the national stock exchanges and certain analyst coverage of, and reports on, the Company. The actual number of shares that vest may be 0% to 100% of the 200,000 performance-based RSUs granted, depending on the achievement of the performance measures. The unvested portion of the time-based or performance-based RSUs will generally be forfeited upon termination of employment. In the case of a change in control of the Company, if either Messrs. Murphy or Michaels is terminated without cause or terminate their employment for good reason during the 12 month period following the change in control, vesting will be accelerated with respect to both the time-based and performance-based RSUs.

In connection with the issuance of the RSUs, the executive officers were issued an executive incentive award agreement. The executive incentive award agreement provides that the executive officer will be allowed to pay applicable federal and state withholding taxes by returning an equivalent number of shares to the Company for cancellation on the applicable vesting date. If the executive officer returns shares to the Company for cancellation on an annual vesting date to cover his federal and state withholding taxes, the executive officer will automatically be issued on such vesting date a stock option. The number of shares of common stock subject to a stock option will be equal to the number of shares the executive returns to the Company as payment for applicable federal and state withholding taxes and will be fully vested. The exercise price of the stock option will be equal to the closing sale price of the Company's common stock on the applicable vesting date.

**All Other Compensation.** The amounts reflected in the All Other Compensation column of the summary compensation table includes relocation expenses and excludes payments made for the reimbursement of medical insurance premiums, the aggregate amount of which is less than \$10,000.

**Outstanding Equity Awards as of December 31, 2012.**

The following table shows certain information regarding outstanding equity awards as of December 31, 2012 for the Named Executive Officers.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested (\$)(2)
Keith Murphy					400,000	1,040,000
Barry Michaels		62,500	2.25	04/18/2022	562,500	1,462,500
	79,687		2.10	8/23/2022		
Sharon Presnell		672,192	0.08	10/14/2021		
Eric David		600,000	1.65	07/23/2022		
Michael Renard		600,000	1.65	07/23/2022		

**Table of Contents**

- (1) The right to exercise the above stock options generally vests 25% on the first anniversary of the date of the grant, with the remaining rights vesting quarterly over the remaining three years. The vesting of the option shares granted to each of these executive officers will accelerate upon the executive's termination or involuntary termination within 12 months of a change in control of the Company.
- (2) The market value of the RSUs is determined by multiplying the number of shares underlying the RSUs by the closing price for our common stock of \$2.60 on December 31, 2012.

**Employment Arrangements with Officers and Directors**

We entered into an employment agreement with Mr. Murphy in February of 2012. The terms of Mr. Murphy's employment agreement provide for him to receive a base salary per year as determined by the Board or a committee of the Board. The term of the employment agreement expired after one year from the effective date, and automatically renews thereafter, unless we provide Mr. Murphy advanced notice of nonrenewal. Mr. Murphy is also eligible to participate in our annual bonus plan and other short-term incentive compensation plans established for our senior executives by our Board or the Compensation Committee. Mr. Murphy is also entitled to participate in our equity incentive awards plans.

Pursuant to the terms of their respective offer letters, Mr. Michaels, Ms. Presnell and Mr. Renard are entitled to certain severance benefits in the event of termination for any reason other than cause. Provided that Mr. Michaels, Ms. Presnell or Mr. Renard execute the Company's form Release and Non-Disparagement Agreement in connection with any such termination, each is entitled to three months of his or her respective salary and benefits plus an additional two weeks of salary and benefits for each fully year of employment, up to a maximum of six months of total salary and benefits paid.

**Director Compensation**

Our directors play a critical role in guiding our strategic direction and overseeing the management of the Company. Ongoing developments in corporate governance and financial reporting have resulted in an increased demand for such highly qualified and productive public company directors. The many responsibilities and risks and the substantial time commitment of being a director of a public company require that we provide adequate incentives for our directors' continued performance by paying compensation commensurate with our directors' workload. Our non-employee directors are compensated based upon their respective levels of Board participation and responsibilities, including service on Board Committees. Mr. Murphy, our President and Chief Executive Officer, receives no separate compensation for his service as a director.

The following table sets forth compensation earned and paid to each non-employee director for service as a director during 2012, 2011 and 2010.

**DIRECTORS COMPENSATION TABLE**

Name	Year	Fees Earned or Paid in Cash (\$)	Option Awards (\$)	Stock Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Robert Baltera, Jr.	2012	24,875	52,747				77,622
Andras Forgacs	2012	21,250	52,747				